EFFICACY OF RESORBABLE (POLYCAPROLACTONE) MESH IN THE TREATMENT OF ORBITAL BLOW OUT FRACTURES

A Dissertation submitted in

partial fulfilment of the requirements

for the degree of

MASTER OF DENTAL SURGERY

BRANCH – III

ORAL AND MAXILLOFACIAL SURGERY

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

Chennai – 600 032

2010 - 2013

CERTIFICATE

This is to certify that **Dr.M.LAAVANYA**, Post Graduate student (2010-2013) in the Department of Oral and maxillofacial surgery, Tamilnadu Government Dental College and Hospital, Chennai-600 003, has done dissertation titled "EFFICACY OF RESORBABLE (POLYCAPROLACTONE) MESH IN THE TRATMENT OF ORBITAL BLOW OUT FRACTURES" under our direct guidance and supervision in partial fulfillment of the regulation laid down by **The Tamilnadu Dr. M.G.R. Medical University, Guindy, Chennai-32** for **Master of Dental Surgery**, Oral and Maxillofacial Surgery (Branch III) Degree Examination.

GUIDED BY

Prof.Dr.G. UMA MAHESWARI. M.D.S.,

Prof & H.O.D, Department of Oral and Maxillo Facial Surgery

Tamilnadu Government Dental College & Hospital

Chennai - 600 003.

Prof. Dr.K.S.G.A.NASSER M.D.S.,

Principal

Tamilnadu Government Dental College & Hospital,

Chennai - 600 003.

DECLARATION

I, **Dr.M.LAAVANYA**, do hereby declare that the dissertation titled **"EFFICACY OF RESORBABLE (POLYCAPROLACTONE) MESH IN THE TREATMENT OF ORBITAL BLOW OUT FRACTURES"** was done in the Department of Oral and Maxillo Facial Surgery, Tamil Nadu Government Dental College & Hospital, Chennai 600003. I have utilized the facilities provided in the Government dental college for the study in partial fulfillment of the requirements for the degree of Master of Dental Surgery in the speciality of Oral and Maxillo Facial Surgery (Branch III) during the course period 2010-2013 under the conceptualization and guidance of my dissertation guide, Prof. Dr. G.UMA MAHESWARI,M.D.S.,

I declare that no part of the dissertation will be utilized for gaining financial assistance for research or other promotions without obtaining prior permission from the Tamil Nadu Government Dental College & Hospital.

I also declare that no part of this work will be published either in the print or electronic media except with those who have been actively involved in this dissertation work and I firmly affirm that the right to preserve or publish this work rests solely with the prior permission of the Principal, Tamil Nadu Government Dental College & Hospital, Chennai 600 003, but with the vested right that I shall be cited as the author(s).

Signature of the PG student *Signature of Guide & Head of the Department*

Signature of the Head of the Institution

TRIPARTITE AGREEMENT

This agreement herein after the "Agreement" is entered into on this day 26.12.12 between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai - 600 003, (hereafter referred to as, 'the college')

And

Dr. G.UMA MAHESHWARI, aged 58 years working as P**rofessor & H.O.D** in the Department of Oral & Maxillofacial surgery, at the college, having residence address at T.Nagar, Chennai.60000. (here in after referred to as the Principal investigator')

And

Dr.M.LAAVANYA aged 29 years currently studying as **Post Graduate Student** in the Department of Oral & Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai-03 (herein after referred to as the 'PG Student and co-investigator').

Whereas the PG student as part of his curriculum undertakes to research on **"EFFICACY OF RESORBABLE (POLYCAPROLACTONE) MESH IN THE TREATMENT OF ORBITAL BLOW OUT FRACTURES"** for which purpose the Principal Investigator shall act as principal investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG student as to the extent possible as a Co-investigator

Whereas the parties, by this agreement have mutually agreed to the various issues including in particular the copyright and confidentiality issues that arise in this regard.

Now this agreement witnessed as follows

1. The parties agree that all the Research material and ownership therein shall become the vested right of the college, including in particular all the copyright in the literature including the study, research and all other related papers.
2. To the extent that the college has legal right to do go, shall grant to licence or assign the copyright so vested with it for medical and/or commercial usage of interested persons/entities subject to a reasonable terms/conditions including royalty as deemed by the college.
3. The royalty so received by the college shall be shared equally by all the three parties.
4. The PG student and Principal Investigator shall under no circumstances deal with the copyright, Confidential information and know – how - generated

during the course of research/study in any manner whatsoever, while shall sole west with the college.

5. The PG student and Principal Investigator undertake not to divulge (or) cause to be divulged any of the confidential information or, know-how to anyone in any manner whatsoever and for any purpose without the express written consent of the college.
6. All expenses pertaining to the research shall be decided upon by the Principal Investigator/Co-investigator or borne sole by the PG student.(co-investigator)
7. The college shall provide all infrastructure and access facilities within and in other institutes to the extent possible. This includes patient interactions, introductory letters, recommendation letters and such other acts required in this regard.
8. The Principal Investigator shall suitably guide the Student Research right from selection of the Research Topic and Area till its completion. However the selection and conduct of research, topic and area of research by the student researcher under guidance from the Principal Investigator shall be subject to the prior approval, recommendations and comments of the Ethical Committee of the College constituted for this purpose.
9. It is agreed that as regards other aspects not covered under this agreement, but which pertain to the research undertaken by the PG student, under guidance from the Principal Investigator, the decision of the college shall be binding and final.
10. If any dispute arises as to the matters related or connected to this agreement herein, it shall be referred to arbitration in accordance with the provisions of the Arbitration and Conciliation Act, 1996.

In witness where of the parties herein above mentioned have on this the day month and year here in above mentioned set their hands to this agreement in the presence of the following two witnesses.

College represented by its **Principal** **PG Signature**

Witnesses **Student Guide**

1.

2.

ACKNOWLEDGEMENT

I am greatly indebted to ***Prof. Dr. G.Uma Maheswari*** *M.D.S, Professor and HOD, Department of Oral & Maxillofacial Surgery, Tamilnadu Govt Dental College and Hospital for teaching me the art of surgery during the period of my study. Words cannot express the contribution and relentless encouragement given by this humble and luminous soul, to whom I will be obliged forever.*

I am very much grateful to ***Prof.Dr. B. Saravanan, M.D.S.,*** *Professor, Department of Oral & Maxillofacial Surgery for his unrestricted help and advice throughout the study period.*

I express my sincere thanks to ***Prof.Dr.D.DuraiRaj, M.D.S,*** *Professor, Department of Oral and Maxillofacial Surgery, for his valuable guidance and encouragement, throughout my post graduation period.*

I offer with profound respect and immense gratitude my heartfelt thanks to ***Prof. Dr. K.S.G.A Nasser M.D.S,*** *Principal, Tamilnadu Govt Dental College and Hospital, for his constant encouragement and support throughout my endeavour during my postgraduation period.*

I am bound to express my thanks to ***Dr.D.Karthikeyan M.D.S*** *, Assistant Professor, Department of Oral and Maxillofacial Surgery, my co-guide, who has been my driving force and helped me throughout my dissertation till its completion.*

I express my special thanks to ***Dr.S.B.Sethurajan M.D.S, Dr.Suresh KumarM.D.S,*** *the assistant professors of my department for their timely help during the course of study.*

I express my gratitude to the ***Regional Govt. Institute of Ophthalmology*** *for doing the ophthalmological examination for all my patients pre & post operatively*

Narrow border of language could never express my respect and gratitude to all the patients who co-operated with me for this study.

I dedicate this study to my parents ***Mr.Marimuthu*** *&* ***Mrs. Veni****, my husband* ***Er.Jayaprakash*** *, my sister* ***Er.Charanya****, for their unconditional love and concern. I also offer my heartfelt thanks to my in-laws* ***Mr.Kasilingam*** *&* ***Mrs.Mala****, my* ***Brother in Laws*** *and my* ***Friends*** *for their moral support.*

Last but not the least I would like to seek the ***blessings of the Almighty*** *without whose grace this endeavour wouldn't have been possible.*

INSTITUTIONAL ETHICAL COMMITTEE

Tamil Nadu Government Dental College and Hospital, Chennai - 3
Telephone No. 044 2534 0343
Fax 044 2530 0681

Ref.No.0430/ DE/ 2010 Date: 26.11.2012

Title of the work: "Efficacy of Resorbable Mesh (Poly Caprolactone) in the treatment of orbital blow out fractures"

Principal investigator: Dr.M.Laavanya,
III Year MDS

Department : Oral and Maxillofacial Surgery,
Tamil Nadu Government Dental College and Hospital, Chennai - 3

The request for an approval from the Institutional Ethical Committee (IEC) considered on the IEC meeting held on 30-04-2012 at the Principal's Chambers Tamil Nadu Government Dental College and Hospital, Chennai – 3 and subsequent to your modification letter dated 26.11.2012

"Advised to proceed with the study"

The Members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above , submitted by the principal investigator.

The principal investigator and their team are directed to adhere the guidelines given below:

1 .You should get detailed informed consent from the patients / participants and maintain confidentiality

2. you should carry out the work without detrimental to regular activities as well as without extra expenditure to the Institution or Government.

3 You should inform the IEC in case of any change of study procedure , site and investigation or guide.

4. You should not deviate from the area of work for which you have applied for ethical clearance

5. You should inform the IEC immediately in case of any adverse events or serious adverse reactions. You should abide to the rules and regulations of the institution (s)

6. You should complete the work within the specific period and if any extension of time is required, you should apply for permission again and do the work.

7 .You should submit the summary of the work to the ethical committee on completion of the work.

8. You should not claim funds from the Institution while doing the work or on completion.

9.You should understand that the members of IEC have the right to monitor the work with prior intimation

10. Your work should be carried out under the direct supervision of your Guide / Professor.

SECRETARY 26/11/12

CHAIRMAN 26/11/12

CONTENTS

1.	INTRODUCTION	1
2.	AIM OF THE STUDY	5
3.	SURGICAL ANATOMY	6
4.	REVIEW OF LITERATURE	9
5.	MATERIALS AND METHODS	26
6.	SURGICAL TECHNIQUE	31
7.	CASE REPORTS	33
8.	OBSERVATION & RESULTS	51
9.	DISCUSSION	56
10.	SUMMARY & CONCLUSION	61
11.	BIBLIOGRAPHY	
12.	ANNEXURE	

ABSTRACT

BACKGROUND

Maxillofacial trauma is one of the most commonly reported entities in oral & maxillofacial surgery. Management of orbital fractures is a challenging problem for the surgeon.

AIM

To assess the outcome of use of resorbable (polycaprolactone) mesh [Osteomesh] in the reconstruction of orbital floor in orbital blow out fractures.

OBJECTIVES

Reconstruction of the orbital floor defect to support the globe and the orbital contents.

Restoration of the orbital volume to correct enopthalmos, a consequence of orbital blow out fractures.

METHODS

In the study, six patients with orbital floor fractures were taken up for surgery. Surgical exploration of the orbital floor fracture was done and reconstruction of the fractured floor defect was done by placing resorbable (polycaprolactone) mesh. The associated zygomatico maxillary complex fracture was also reduced and fixed.

OBSERVATION & RESULTS

All the patients were examined clinically post operatively. Out of the six patients, one patient had ectropion of the lower lid which resolved in three weeks of time. Ophthalmologic assessment post operatively revealed resolution of diplopia which was present in two patients. Ocular movement which was restricted in one patient also got restored. Comparison of pre and post operative orbital volume revealed restoration of volume in one patient out of the six patients.

INTERPRETATION AND CONCLUSION

Based on the results obtained, resorbable (polycaprolactone) mesh was found to be good material for reconstruction of the orbital floor. However, a further study with an increased study sample is necessary to validate its use.

Keywords: orbital floor fracture, orbital blow out fracture, resorbable mesh

INTRODUCTION

INTRODUCTION

A harmonious symmetric relationship between the paired and unpaired structures of the face forms the first impression from an esthetic viewpoint. The three dimensional position of the eyes, their color and synchronous eye movement are major contributors to this overall picture. The eyes should be bright and reflect light; they are the windows to the soul[46].

The complex structures of the orbital walls and the prominent position of the orbit within the craniofacial skeleton predisposes the region to multiple orbit fractures including its walls. Orbital floor fractures can vary from a simple fracture, which does not require any surgical intervention, to complicated fractures with displaced bone fragments, diplopia and enopthalmos leading to surgical intervention[75].

Lang in **1889** was the first to record a description of a case of orbital blow out fracture with enopthalmos. In **1957**, **Smith and Regan[78]** coined the term ***"Blow Out fracture"***. Smith defined the term as fracture of the floor of the orbit which may be accompanied by displacement of the orbital contents into the maxillary sinus. Based on the involvement of the orbital rim fracture along with floor fracture, Converse and Smith in 1960 introduced the concept of ***pure blow out*** and ***impure blow out*** fractures[11].

Unfavorable esthetics and functional outcomes are frequent when orbital floor fractures are treated inadequately. The treatment consists of spanning the floor defect with a material that can provide structural support and restore the orbital volume. The material should also be biocompatible with the surrounding tissues and moldable to fit the orbital

floor. Although various autografts and allografts have been used, there is still no consensus on the ideal reconstruction material for orbital floor defects[80].

Two decisions are essential for a favorable outcome in the management of orbital fracture. First is the identification of floor defect followed by selection and placement of appropriate materials for reconstruction. Management of orbital fractures, whether pure blow out fractures or components of associated zygomatic bone fractures is a challenging problem for the oral and maxillofacial surgeons.

Wide ranges of choices are available regarding the materials used for orbital floor reconstruction. They can be classified as autografts, allografts or alloplasts. Autografts include periosteum, rib grafts, nasoseptal cartilage, auricular cartilage, iliac bone graft, mandibular bone graft, calvarial graft. Allograft materials include lyophilized dura and lyophilized cartilage[44].

Alloplasts can be further classified as non resorbable and resorbable materials. Titanium mesh, Teflon, Medpore, silicone come under the non resorbable category. Resorbable materials include poly- L- Lactide, polydioxanone, polycaprolactone, polyglactin-910 and polyglycolic acid[44].

Although autogenous bone grafts provide framework for orbital walls, they carry the main disadvantage of donor site morbidity including nerve and blood vessel injuries, gait disturbance, cosmetic disturbance, and donor site pain[22]. Non resorbable alloplasts become as permanent foreign bodies and can cause late complication such as infection, migration of implants, extrusion of implant and also residual diplopia[44].

To overcome the disadvantages of the above materials, resorbable implants can be used. These are biocompatible and also have sufficient biomechanical resistance and can be resorbed without causing foreign body reaction. Resorbable mesh is easy to sculpt to fit to the defect and the surgical time is decreased significantly. The main advantage is the use of this material in maintaining the contents of the orbital cavity against herniation during the initial phase of healing and complete resorption from the region after it is no longer needed[60].

In our study, we decided to use resorbable mesh made of polycaprolactone (PCL) [Osteomesh] for orbital floor reconstruction. Polycaprolactone (PCL) belongs to the family of aliphatic polyesters and has been widely used as a suture material (Monocryl) and as a contraceptive implant[13]. It is found that out of all the available resorbable biomaterials, PCL has an above average tensile strength. At room temperature, PCL is ductile as compared to PGA and PLLA which are brittle in nature which allows ease of handling. PCL scaffold has got a controlled and slow degradation profile, without the sacrifice of construct collapse. This allows sufficient mechanical strength to be maintained after implantation[23].

Currently, PCL is regarded as a non-toxic and tissue compatible material. PCL is highly compatible with human osteoblasts and craniofacial bone tissues and has proven to be successful in orbit reconstruction[23,35]. One main advantage of this material over other biodegradable implants is that its scaffold allows easy infiltration of osteoblasts. The scaffold has a porosity of 85% which allows for osteoblasts to infilterate completely. It is because of this structure that allows new bone formation to form readily and allows cell to cell signaling for further remodeling, proliferation and diffusion[58].

Through this prospective study, we intend to evaluate the usefulness of resorbable (polycaprolactone) mesh [Osteomesh] in the restoration off orbital floor defects.

AIM

AIM OF THE STUDY

The aim of the present study is to assess the outcome of use of resorbable polycaprolactone mesh [Osteomesh] in the reconstruction of orbital floor in orbital blow out fractures.

SURGICAL ANATOMY

SURGICAL ANATOMY

It is very important to know and appreciate the anatomy of the orbit to understand the injuries sustained by the orbit and to postulate how to reconstruct it. The orbit can be anatomically classified into many ways. It has been described in relation to its bony components, the periocular soft tissues, the globe and the protective soft tissue apparatus consisting of the upper and lower eyelids and the lacrimal apparatus.

The bony orbit comprises of seven bones namely:

1. Zygoma
2. Maxilla
3. Lacrimal bone
4. Frontal bone
5. Ethmoid bone
6. Palatine bone
7. Sphenoid bone

The orbit contains the eye and its accessory structures, but the globe of the eye only takes up one quarter of the volume of the orbit. The orbit is a quadrangular pyramid with its base on the facial surface. Its apex is the optic foramen and the medial end of the superior orbital fissure. The medial wall made of ethmoid bone is almost paper thin of about 0.2 to 0.4mm.

The orbital rim is composed of cortical bone. Its strength arises from its circum orbital continuity.

The floor is almost triangular with rounded corners, being narrower posteriorly and merging medially with the almost quadrilateral plate of the ethmoid bone. The floor is not horizontal but slopes upwards and medially at 45 degree and ascends posteriorly at about 30 degree. The floor is very thin being almost 0.5mm in most areas and is further weakened by the presence of infra orbital groove and canal. It is concave anteriorly and convex posteriorly. Medially there is no distinct border. The orbital floor behind the orbital rim is initially concave until a point just behind the equator of the globe. Posteriorly, it becomes convex upwards inclining to about 30 degrees creating the retrobulbar constriction of the orbit. The inferior orbital fissure separates the lateral wall and the floor of the orbit. It is roughly 2cm long and runs postero-medially.

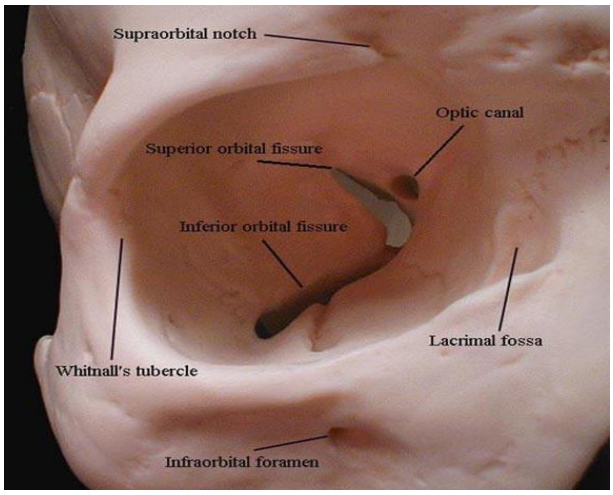
There is a 45 degree inclination from the lateral to the medial wall and antero-medially and postero-medially to it there is a bulge called Hammer's key area, which is a very important area for graft placement to efficiently correct enopthalmos. The inferior and the lateral wall can be safely dissected for about 35mm to reach the area.

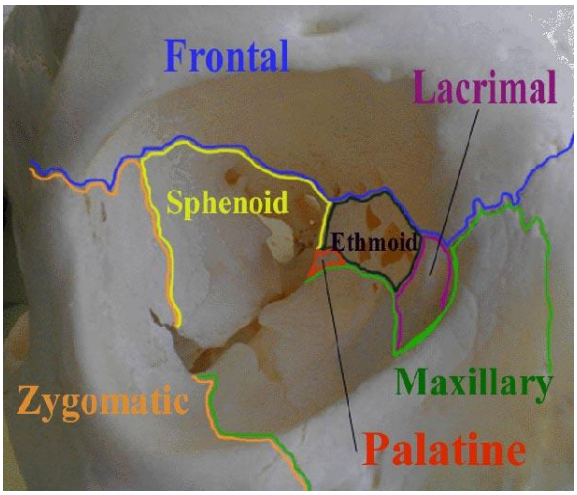
The inferior orbital margin is clearly defined on its outer aspect and is readily palpated but the inner third is more rounded. It is not able to withstand direct force in the central and medial areas because of the proximity of the underlying maxillary antrum and the closely related infra orbital canal. Just within the rim at the junction of the outer two thirds and the inner one third, there is a small depression which marks the origin of the inferior oblique muscle, the only extra ocular muscle which does not arise from the back

of the orbit. This part of the inferior oblique rim is often fractured producing associated disruption of the muscle and subsequent diplopia.

Rontal et al (1979)[78] studied 48 orbits in 24 skulls to determine the relationship of important structures to determine the relationship of important structures of the orbit to well defined landmarks in the wall. By summarizing the useful measurements given by them, it may be stated that a subperiosteal dissection may be safely extended for a distance of 25mm posterior to the inferior and lateral rim and for a distance of 30mm from the superior rim and the anterior lacrimal crest. The distance from the infra orbital foramen to the midpoint if inferior orbital fissure is around 24mm.

SURGICAL ANATOMY





REVIEW OF LITERATURE

REVIEW OF LITERATURE

Description of orbital floor fractures:

Lang (1889) [78] described the first case of orbital blow out fracture in literature.

Pfeiffer (1943) [52] investigated 120 cases of fracture of facial skeleton involving the orbit. Of these, he observed traumatic enopthalmos in 54 cases. He considered that this condition developed as a result of the globe being forced against the thin posterior portion of the orbital floor at the point where it slopes upward.

Smith & Regan (1957) [68] coined the term Blow out fracture for isolated fractures of the orbital floor produced from hydraulic forces secondary to posterior displacement of the globe and compression of periorbital fat.

Dingman & Natwig (1964) [78] coined a condition termed blow in fracture. They described a rare phenomenon in which elevation of fractured fragments of the orbital floor occurs but the orbital rim remains intact.

Mustarde (1968) [41] related the displacement of the globe in orbital fractures to the suspensory ligament of Lockwood. When the suspensory ligament is disrupted, they lead to alteration in the position of the globe. Also repair of the Lockwood's ligament is very essential to restore the globe position.

Deutschburger & Kirschner (1971) [78] concluded that a defect of more than 1cm in dimension by tomography necessitates surgical intervention. This conclusion was derived after observation of 47 cases. They demonstrated that the size of the orbital floor defect to be the cardinal and guiding factor for determining the need for surgical intervention.

Lew D (1997) [34] divided the orbital floor defects that require treatment into three broad categories. The first one is a completely disrupted orbital floor devoid of any bony material to support a graft ; the second one being a severely disrupted floor with sufficient amount of bone in the lateral, medial and posterior areas to support the graft material and the third one was classified as a trap door defect.

Roncevic and Malinger (1981) [54] states that when there is evidence of prolapse of the orbital contents into the maxillary antrum as in the case of impure fractures with zygoma or Lefort fracture, open reduction with floor exploration has to be done.

Manson (1985) [36] described that enopthalmos post orbital wall fractures is mainly due to the displacement of the intraconal orbital fat outside the muscle cone that occurs following orbital fractures.

Tessier (1986) [78] stressed that a wide dissection of the periorbital tissues around the floor defect is very necessary especially in cases of noted enopthalmos or late repair of orbital fractures.

Pearl (1987) [78] reported certain predisposing factors for causing enopthalmos after conducting a study of orbital fractures in fresh cadavers and chimpanzees. He stated orbital fracture behind the axis of the globe with volumetric displacement and rupture of the musculofascial cone predisposes to enopthalmos.

Parson and Mathog (1988) [78] through their study reported the relationship between orbital volume, displacement of orbital floor and change in globe position. They showed that 1mm of displacement of the orbital floor resulted in 0.4 ml increase in orbital volume and 1.5mm change in global position.

Harris GJ et al (1998) [18] classified indirect orbital floor fractures under three broad categories namely type I, type II, type III and two subtypes based on the status of the fractured bone segment and the soft tissue. Type I consists of trap door fractures in which the bone fragment appears to have aligned almost perfectly after the fracture; Type II consists of fractures in which bone fragments were distracted apart with soft tissues displaced between them and type III consists of fractures in which the displaced bone fragments surrounded displaced soft tissues in all the areas.

Lawrence et al (2000) [30] did a retrospective study on 199 treated cases of orbital floor fractures and through the study, they concluded that impure orbital blow out fracture was caused by high energy trauma and blow out fracture of the pure variety was caused by low energy trauma.

Gonzalez M et al (2010) [15] classified orbital floor fractures as direct and indirect. The authors mention that direct orbital fractures involve and extend the orbital rim whereas indirect orbital floor fractures are orbital floor fractures without involvement of the rim. Indirect orbital floor fractures have been described by several names such as blow out fracture and impure fracture.

Pier Luigi Grenga (2009) [48] retrospectively studied 30 cases to determine if the Hess area ratio is effective in predicting postoperative diplopia in patients undergoing surgery for orbital blowout fracture. To evaluate the ocular motility disturbance, the authors measured the involved ocular motility range by use of a manual Hess screen test before and 4 months after surgery. The percentage of Hess area ratio % was used to express the range of ocular motility in a numerical value. All patients with preoperative Hess area ratio 85% had no postoperative diplopia and most patients (57%) having a preoperative Hess area ratio 65% had postoperative diplopia. When

the Hess area ratio was between 65% and 85%, surgical outcomes were variable and most patients (55%) described no problematic diplopia in the peripheral visual field. Through the study, they concluded that The Hess area ratio is a useful procedure to convert Hess graphic representation in a numerical value so that Hess chart data can be compared among clinicians and used to predict surgical outcomes in patients undergoing surgery for orbital blow-out fractures.

Radiologic and tomographic investigations:

Crikelar et al (1972) [78] stated that with the use of plain films for studying orbital floor fractures, the fractures were over diagnosed. They advised surgical intervention in fractures evident in tomogram with persistent diplopia and enopthalmos after 2 weeks.

Hammerschlag et al (1982)[52] by using 2mm thick sagittal CT scan sections and lateral tomogram, a 100% accurate diagnosis of orbital floor fractures can be done.

Zonneeld & Korneef (1986) [78] described a specific position for sagittal CT examination of the orbit parallel to the optic nerve. The authors also used a direct tri plane high resolution CT inorder to demonstrate scar tissue and they emphasized that ocular motility disorders occurs because of connective tissue disturbance in the orbit and not due to entrapment of the muscle.

Lee et al (1993) [32] evaluated the change in orbital volume in cases of blow out fracture by using quantitative CT and they concluded that a change in volume of the bone over 8% implies poor cosmetic outcome and indicates a need for surgical correction in such cases.

Noah et al (1994) [43] evaluated the ability to diagnose orbital floor fracture with the use of trans-antral endoscopy. The authors advocate the use of trans-antral endoscopy in patients whose concomitant injuries may prohibit the use of other diagnostic modalities.

G Ramieri et al (2000) [51] analyzed 25 patients and investigated the morphology and dimensions of the orbit and fat content by image analysis and volumetric estimation from 2D and 3D CT. They stated that post traumatic enopthalmos was commonly related to failure in correcting the orbital volume and reducing the outward dislocation of the posterior orbital floor and was not related to the changes in the fat content.

P Angela Rake et al (2004) [6] advocate the use of a single reformatted oblique sagittal view as an adjunct to coronal CT since it provides additional information with minimal time and requires no additional radiation.

Xianqun et al (2007) [79] conducted a prospective study on 17 patients with who have sustained complex orbital fractures with the help of 3D images and computer generated models. They also calculated the orbital volume using software named Surfacer and they developed a CAD/CAM system inorder to improve the surgical planning in cases of complex orbital floor fracture.

Nicholas and Vaseekaran (2009) [42] suggest the use of cone beam computed tomography in diagnosing and treating isolated fractures of the orbital floor. They state that the use of cone beam CT requires very low radiation when compared with conventional computed tomography.

Surgical intervention:

Dulley and Fells (1975)[78] did a study on 103 patients and found that there was 72% incidence of enopthalmos in patients treated 6 months or later after the orbital injury when compared with patients treated with 14 days of trauma where the incidence of enopthalmos was 20%.

Hawes and Dortzbach (1983)[52] emphasized on the importance of surgical intervention within two weeks of trauma for fractures involving more than half of the floor along with persistent diplopia within 30 degrees of the primary gaze.

Anderson PJ et al (1995) [2] stated that the orbital floor fractures in children are found to be relatively common in comparison with adults. They recommend that in children surgical intervention should be performed within a few days of injury in an attempt to reduce post-operative enopthalmos. They stated that the late complications resulting from injuries sustained in childhood include diplopia, chocolate cyst formation, and development of midface hypoplasia in association with midface fractures. It has been suggested that there is an increased risk of diplopia following orbital floor fractures in children so a long term follow up is recommended.

Damir B.Matic et al (2007) [12] conducted a four year review in patients with orbital floor fractures who underwent conservative management. Through the study they observed that a height to width ratio of the inferior rectus muscle on a coronal CT scan of greater than or equal to 1.00 is predictive of late enopthalmos.

Nicholas A. Drage (2008)[42] demonstrated the use of Cone Beam Computed Tomography (CBCT) in the management of orbital floor fractures. The main advantage with this imaging modality was the reduction in radiation dosage. The

volumetric data set can be reconstructed into the axial, coronal and sagittal planes. Three-dimensional reconstructions may be made. The limitations of CBCT are that it provides low contrast resolution. By taking into account the volume of tissue irradiated, a conservative estimate of radiation dose using this technique was found to be around 100Sv.10 and they concluded that CBCT is useful in the management of fractures of the orbital floor with low radiation dosage to the patient.

Simon et al (2010) [66] reported from their 12 year study that when patients with orbital fractures who underwent early repair were compared with those who underwent non-surgical management, did not show significant difference in the post-operative outcome.

Surgical approaches:

Transcutaneous approach:

Converse (1994)[14] popularized the subciliary incision. Here the incision was placed in the skin several mm below the lid margin in a skin crease.

Antonyshyn (1989)[7] stated that following a subciliary approach, 16.6% ectropion and scleral show occurred.

Transconjuctival approach:

McCord and Moses (1970)[52] popularized transconjuctival approach along with lateral cantholysis called the swinging lower eyelid flap that suited adequate exposure of the orbital floor.

Tessier and Converse (1973) [52] popularized the use of transconjuctival approach for the correction of congenital deformity involving the orbit.

Reconstruction of orbital floor:

Kaye (1966) [78] described the use of bone from the anterior wall of maxillary antrum as a graft material for orbital floor reconstruction using Caldwell-Luc approach.

Hotte (1970) [78] suggested the use of bone from the mastoid on the contralateral side for the purpose of reconstruction of the orbital floor.

Iizuke (1991)[19] reported the use of Polydioxanone which was proved to be satisfactory but its resorption rate made it difficult to predict and compensate for the drop of level of globe.

Rubin et al (1992)[78] advocated the use of a soft titanium mesh to support large bone grafts in case of extensive orbital floor fractures to restore the orbit to its normal volume.

Leon et al (1994)[33] reported a solitary lag screw technique for the purpose of securing the bone grafts such as calvarial bone grafts and maxillary antral bone grafts to the intact orbital rim. They found it as a relatively quick, safe and stable method.

Kalk W WI et al (1996) [24] retrospectively studied the morbidity of bone harvesting from the inner table of anterior iliac crest. They reported a variety of complications associated with iliac crest bone including chronic pain, sensory loss, hematoma, wound breakdown, contour defect, hernia through the donor site, gait disturbance, instability of the sacroiliac joints. However, their results showed that there was a good

acceptance of this one, and the morbidity was low and so they concluded that bone harvesting from the inner table of the anterior iliac crest is a good option for reconstruction of bone defects.

Krishna et al (1997) [73] showed the usefulness of mandibular symphysis as a source of bone graft for the reconstruction of the orbital floor. A retrospective study was conducted on 16 patients who isolated orbital blow out fractures. Symphyseal bone grafts were used when the defects were less than 2cm. results showed that during a mean follow up of 12 months, patients had no post-operative complaints. They stated that its contour is suitable for use in orbital floor reconstruction and merits consideration when autogenous bone grafts are considered for floor defects less than 2cm.

Lee HH et al (1998) [31] evaluated the use of autogenous maxillary bone for the repair of orbital floor defects secondary to blunt facial trauma. They did a study on forty one consecutive patients who underwent repair of orbital floor fractures with maxillary antral wall bone grafts. On follow up, none of the patients presented with any evidence of orbital dystopia or complications related to the implant or donor site. They concluded that the use of maxillary antral bone graft for orbital floor reconstruction is a highly reliable technique that carries minimal morbidity.

Mintz S M et al (1998) [39] compared the contour of the coronoid process with the orbital floor using skulls and suggested its use as a bone graft or orbital floor reconstruction. Their study results showed that the measurements and contour comparisons of the right orbital floor with the left lateral cortex of the coronoid process and vice versa showed a close match in contour and dimension. They stated that with minimal trimming of the peripheral bony margins and medial coronoid

cortical plate, coronoid process makes an excellent donor graft site for the reconstruction of orbital floor deformities.

Montazem et al (2000) [40] quantified the amount of bone graft material present in the mandibular symphysis as well as to determine the maximal size of the corticocancellous bone block that can be harvested while avoiding mental nerve injury, tooth injury, and simultaneously preserving the preoperative facial contour. The average block size was 20.9x9.9x6.9mm; the smallest was 21.0x6.5x6.0mm; and the largest 25.0x13.0x9.0mm. Based on the study, it was apparent that the mandibular symphysis can be reliably selected as the harvest site in a variety of oral and maxillofacial reconstructive procedures.

Siddique et al (2002) [65] evaluated the results of cranial (membranous) versus iliac crest (endochondral) bone grafts as implants to correct post traumatic globe malposition and/or diplopia. Twenty two patients underwent 25 orbital floor reconstructions with bone for enopthalmos, hypopthalmos, and diplopia after trauma to the orbit. Nine cranial grafts and sixteen iliac crest grafts were placed. They stated that there is no difference in the ability of cranial and iliac crest bone grafts to correct post traumatic enopthalmos.

Gungormus et al (2002) [16] in their study quantified the amount of bone graft material present in the anterior part of the ascending ramus while avoiding the inferior alveolar neurovascular bundle injury. From 16 samples of dry skull, bone material was taken and the dimension, surface area, and volume of bone graft was measured and evaluated. The results showed that the average dimension of bone material obtained was 37.60 x 33.17 x 22.4 x 9.5 mm; the average bone volume was 2.36 ml; and the average surface area was 495.13mm^2. They concluded that the anterior part of the

ascending ramus can be used as the donor site for reconstruction of small bone defects in the oral and maxillofacial region.

Sandor et al (2003)[56] stated that the iliac crest is favored extra oral donor site because of its accessibility and the large quantity of bone available. They concluded that the anterior ilium allows the graft harvest to be performed simultaneously with the preparation of the recipient site, thereby reducing operative and anesthetic time.

Jank S et al (2003)[21] investigated whether a flexible, biodegradable material (Ethisorb) shows better long term results with regard to diplopia, bulbous motility, and exophthalmos/enopthalmos compared to the use of lyophilized dura patches and polydioxanone (PDS) foils. The use of Ethisorb resulted in a significantly lower incidence of exophthalmos 3 months after surgery compared to PDS. They concluded that the low rate of bulbous motility post operatively demonstrates acceptable results in using Ethisorb in the floor of the orbit.

Yavuzer et al (2004)[80] in their study evaluated the applicability of solvent preserved cadaveric cranial bone graft and its preliminary results in the reconstruction of orbital floor fractures. Twenty five orbital floor fractures of 21 patients who underwent surgical repair with cranial bone graft during a 2 year period were included in the study. This study showed that solvent preserved bone, which is a non-synthetic, human originated, processed bio implant, can be safely used in orbital floor repair and can be considered as another reliable alternative.

Potter J K et al (2004)[50] elaborated on the various requirements of an implant material to be used as a graft in orbital floor reconstruction. They further mentioned if alloplastic, it should be cost effective and capable of sterilization without deterioration of its chemical composition. The material should be easily cut and sized in the

operating room, and be able to be shaped to fit orbital contours and retain its new form without memory. It should allow fixation to host bone by screws, wire, suture or adhesive. It should not potentiate growth of microorganisms nor promote resorption of underlying bone or distortion of adjacent tissues. The material should be permanently accepted, and if resorbable, completely resorb with replacement by host bone.

Kosaka M et al (2004)[27] assessed the efficacy of bone grafting from the mandibular outer cortex for reconstruction of orbital walls. They concluded that bone harvest from the mandible affords several advantages including ease of harvest, ease of trimming, appropriate size and curvature, absence of functional disability, no secondary deformity, no visible scars, post-operative immobilization not necessary, absence of post-operative difficulties with respect to breathing and walking and rare major complications.

Tanag et al (2004)[72] conducted an animal study to investigate the efficacy of injectable calcium phosphate for the reconstruction of orbital floor defects. Orbital floor defects were created in rabbits and were reconstructed using an injectable calcium paste. They concluded that because of the ease of use and structural integrity, calcium phosphate can be used in orbital floor reconstruction.

Kontio R K et al (2006)[26] assessed clinically and radiologically the outcome of internal orbital reconstruction with an iliac bone graft. Twenty four consecutive patients with unilateral orbital floor fractures were enrolled in this prospective study. A medial cortical wall from the anterior ilium was used for reconstruction. Results showed that the resorption rate was high, but most of it was advantageous remodeling and the overall outcome was good.

Bilen B T et all (2006)[10] presented four cases which underwent reconstruction of orbital floor and maxillary anterior wall with a vascularized bone flap following partial maxillectomy. Superficial temporal artery and vein based calvarial bone flaps from the outer tabula were prepared. Without disrupting the integrity of fascia and periosteum, the bone was separated into two segments in the same direction as the blood flow and one was 3cm and other 5 cm. The two bone segments were transferred as one single flap and one segment of the flap was used to reconstruct the orbital floor and the other for reconstruction of the maxillary wall. They concluded that esthetic and functional results were satisfactory.

Al-Sukhun et al (2006)[3] compared the clinical findings on the use of autogenous bone grafts and bioresorbable poly-L/DL –Lactide [P(L/DL)LA 70/30] implants to repair inferior orbital wall defects. The clinical outcome was excellent in in both the groups and the clinical complication in both the groups was enopthalmos followed by diplopia. Taking into account, the availability and advantages of P(L/DL)LA 70/30 implants, they concluded that there is no compromise regarding successful bridging of orbital floor defects using biodegradable P(L/DL)LA 70/30 osteosynthesis.

Yilmaz et al (2007) [81] evaluated the long term results after reconstruction of the orbital floor defects with porous polyethylene. All the fractures were reconstructed with thin and ultrathin porous polyethylene sheets. No implants extruded and there were no signs of inflammatory reaction against porous polyethylene. Based on the results, they concluded that porous polyethylene sheets are reliable safe and effective implants and may be used for reconstruction of the orbital floor fracture with no donor site morbidity or need to fix the implant.

Wang S et al (2008) [77] in a retrospective study investigated the diagnostic methods, therapeutic principles, surgical approach, and materials were used for orbital floor reconstruction. Shaped autogenous bone, titanium mesh and Medpor were respectively implanted in 5 cases, 10 cases and 6 cases. Based on the results, they concluded that titanium mesh can be used in fractures with large defects that were not easy to fix without obvious enopthalmos and porous poly ethylene can be used in fractures where there is a need to restore orbital volume.

Low SW et al (2009) [35] did a study by using Osteoplug™ for covering bur holes created in the cranium during neurosurgical procedures. They found that PCL did not interfere with imaging techniques posy operatively and the slow degrading PCL framework allowed neovascularization to seed for wound healing. The material was found to be biocompatible, capable of facilitating revascularization, osteoinductive and osteoconductive. By two years, the process provided a stable integration of graft material into the bone tissues. They also found that slow-degrading PCL framework allowed neovascularization to seed for wound healing.

Amrani S et al (2010) [4] evaluated the utility of autogenous extended ramus/ coronoid process bone grafts for maxillofacial reconstructive surgery. Based on the results, they concluded that using both the coronoid process of the mandible and the mandibular ramus as a source of autogenous bone graft can provide sufficient bone in quantity and quality for selected maxillofacial reconstructions.

Prowse SJB et al (2010)[66] evaluated the long term outcomes of orbital floor reconstructions with silicones vs. non silicone implants. Outcomes of silicone implants were compared to non-silicone implant materials including titanium mesh, 'Lacta-sorb', Resorb-X, autologous cartilage, and bone graft. They concluded that

appropriate use of silicone implants for orbital floor reconstruction can have good results. They stated that to establish definite guidelines for best surgical practice, particularly amongst synthetic implant materials, prospective study is required.

Asamura S (2010)[8] performed a study on bone regeneration using a periosteum-polymer complex produced by attaching periosteum to a biodegradable polymer sheet. In in this study, patient with orbital floor fractures were evaluated clinically who had undergone reconstruction of orbital floor reconstruction using a periosteum polymer complex produced by applying periosteum to a Hydroxyapatite-[poly (L-lactide3-caprolactone)] (HA-P(CL/LA) sheet and the ilium. Based on the results, they concluded that the anatomical eyeball position and eyeball movement were normal after surgical treatment using the periosteum polymer complex, just as in reconstruction using autologous bone.

Bayat et al (2010)[9] stated that the ideal way of managing and reconstructing the defect in the orbital floor remains controversial. They further stated that the main aim of reconstructing orbital blowout fractures should be to restore the continuity of the orbital floor; to provide a support for the orbital contents; to prevent fibrosis of the damaged walls; and to prevent herniation of the orbital contents into the maxillary or ethmoidal sinuses. They compared autogenous nasal septal cartilage and conchal cartilage as grafts for reconstruction of orbital blowout fractures. Results showed that the patients treated with a nasal septal cartilage graft had significantly better correction of enopthalmos than those treated with conchal cartilage.

Kun Hwang (2010) [28] studied the supporting strength of the curved poly-L-lactic acid (PLLA) sheet and porous polyethylene (Medpor) for reconstruction of orbital floor fractures. Each implant was hung by wire, and the degree of sagging of the implant

was measured using micrometers by the power of a force gauge. They found that both PLLA sheet and Medpor were sufficient for reconstruction of one-half and two-thirds orbital floor fractures with a defective posterior part. But when the supporting power was considered, PLLA sheet was found to be more strong.

Takuya Higashino (2011)[71] did a retrospective study on blow-out fractures in patients reporting at Teikyo University Hospital between July 2004 and May 2007 and also conducted a survey regarding diplopia and enopthalmos for non-operative cases. The authors suggested a new algorithm for treatment of blow-out fractures based the fracture width and the degree of protrusion of the inferior rectus muscle into the maxillary sinus based on the CT findings. They recommended that for medial orbital wall fractures, non-operative treatment is recommended when there is no evidence of enopthalmos and that surgery should be performed only if enopthalmos develops; in cases of punched-out floor fractures, surgical intervention is done when diplopia is present to avoid persistent diplopia and when the fracture width is less than half of the globe and the degree of protrusion of the inferior rectus muscle into the maxillary sinus is half or more of the inferior rectus muscle section and also to prevent enopthalmos; and finally for linear fractures, prompt surgical intervention is planned when any symptoms of entrapment of the orbital contents; in the case of punched-out (medial)/linear (floor) fractures, non-operative treatment is recommended when there is no evidence of entrapment of the orbital contents or of enopthalmos. Surgical intervention should be planned only if enopthalmos develops.

Sueng Min Nam (2011) [61] described reconstruction of the orbital floor slope in cases of orbital floor fractures that prevents postoperative complications, especially post traumatic enopthalmos. Between April 2009 and July 2010 they treated thirty-three patients with orbital floor fractures by reconstruction of the orbital floor slope. The

patients ranged in age from 12 to 54 years. There were 31 males and 2 females. All patients were operated using a transconjuctival approach. Reconstruction of the orbital floor was done using poly-L/D-Lactide sheets in all cases. Preoperatively, it was found that 23 patients (69%) had enopthalmos, and 12 patients (36%) had symptomatic diplopia; of these, enopthalmos was corrected in 20 patients (86%) and diplopia resolved in 10 patients (83%). Extrinsic ocular movement which was impaired preoperatively in 1 patient (3%) resolved after surgery. No patient had impaired visual acuity preoperatively or postoperatively. With the help of this study, they concluded that orbital floor reconstruction considering the orbital floor slope is a safe and reliable method with fewer complications that is more effective at preventing posttraumatic enopthalmos.

Matthias Gierloff (2012) [38] performed orbital floor reconstruction using polydiaxone resorbable material in 194 patients. Patients were divided into three groups based on the area of orbital floor defect. Group I patients had less than 1 cm^2 of orbital floor defect, group II had defect of 1 to 2 cm2 and group 3had defect greater than 2 cm^2. They concluded that PDS is a suitable implant for orbital floor reconstruction and the clinical outcome is better than other biodegradable materials and that they can also be used for orbital floor defects exceeding 2 cm^2.

METHODOLOGY

MATERIALS AND METHODS

The subjects of this prospective study were patients who sustained orbital blow out fractures with associated zygomatico – maxillary complex fracture reporting to the department of oral and maxillofacial surgery, Tamil Nadu Govt. Dental College and Hospital.

METHODS OF COLLECTION OF DATA:

Six patients with orbital floor fractures were included in the study. The procedures to be performed were explained, followed by written informed consent. A detailed history was taken followed by clinical examination. PNS view and CT scan in all the three planes with 3D reconstruction was taken and findings were recorded in a specially prepared case history proforma. Pre operatively surgical defect was measured in the CT scan and volume was measured using Volume share II, an installed application.

Post operatively, all the patients were followed for 2 months to evaluate enopthalmos, diplopia, and any limitation of extraocular movements. The surgical sites were examined for evidence of infection, extrusion of the graft at the orbital rim. Post-operative volume measurement was done for comparison.

INCLUSION CRITERIA:

Patients who have sustained orbital floor fractures and willing to undergo treatment with evidence of the following:

- Diplopia
- Hypoglobus
- Enopthalmos
- Mechanical restriction in ocular motility
- Radiological evidence of floor defect

EXCLUSION CRITERIA:

- Medically compromised patients
- Optic neuropathy or post traumatic blindness
- Previous history of ophthalmic surgery
- Previous history of injury to the globe
- Only eye with vision.

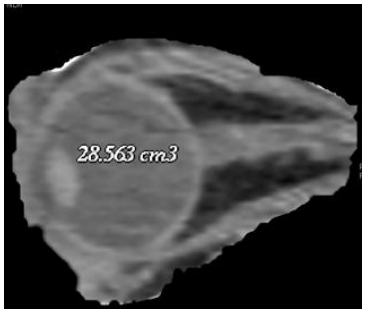
Ethical approval was obtained for the study from the institutional ethical committee and informed consent obtained from each patient in the regional language (Tamil) explaining nature of the surgical procedure and the study.

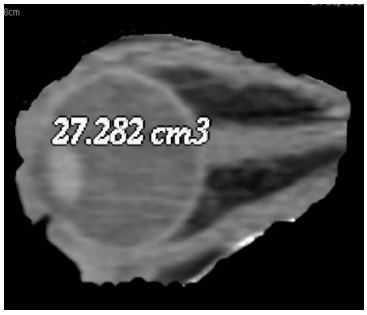
METHOD OF STUDY

PRE-OPERATIVE ASSESSMENT:

A detailed history was obtained from all the patients, clinical examination including general examination and ophthalmologic examination was done, radiograph, CT scan and facial photographs were taken.

CT scan was taken for all the patients using GE Discovery Workstation. Volume of the orbits were measured using Volume share II, an installed application.





CLINICAL EXAMINATION:

Both extra oral and intraoral examinations were to done to assess the injury and make a diagnosis.

The patients were referred to the Regional Institute of Opthalmology, Egmore, Chennai for a detailed ophthalmologic examination including Hess charting for diplopia.

OPTHALMOLOGIC EXAMINATION:

All the patients underwent ophthalmologic examination at the Regional Institute of Opthalmology, Egmore, Chennai. The following were assessed.

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT		
CONJUCTIVA		
CORNEA		
PUPIL		
LENS		
FUNDUS EXAMINATION		
VISUAL ACUITY		
DIPLOPIA		
FORCED DUCTION TEST		
INFRAORBITAL SENSATION		

HESS CHARTING:

INVESTIGATIONS:

All the patients were advised PNS view, CT scans in all the three planes with 3D reconstruction. All routine investigations were done which included bleeding time, clotting time, hemoglobin level, RBC count, total and differential WBC count, platelet count, ESR, PC, RFT, blood grouping, ECG, Chest x ray, HIV.

SURGICAL TREATMENT:

All cases were operated under general anesthesia with nasal intubation in RGGH, Chennai.

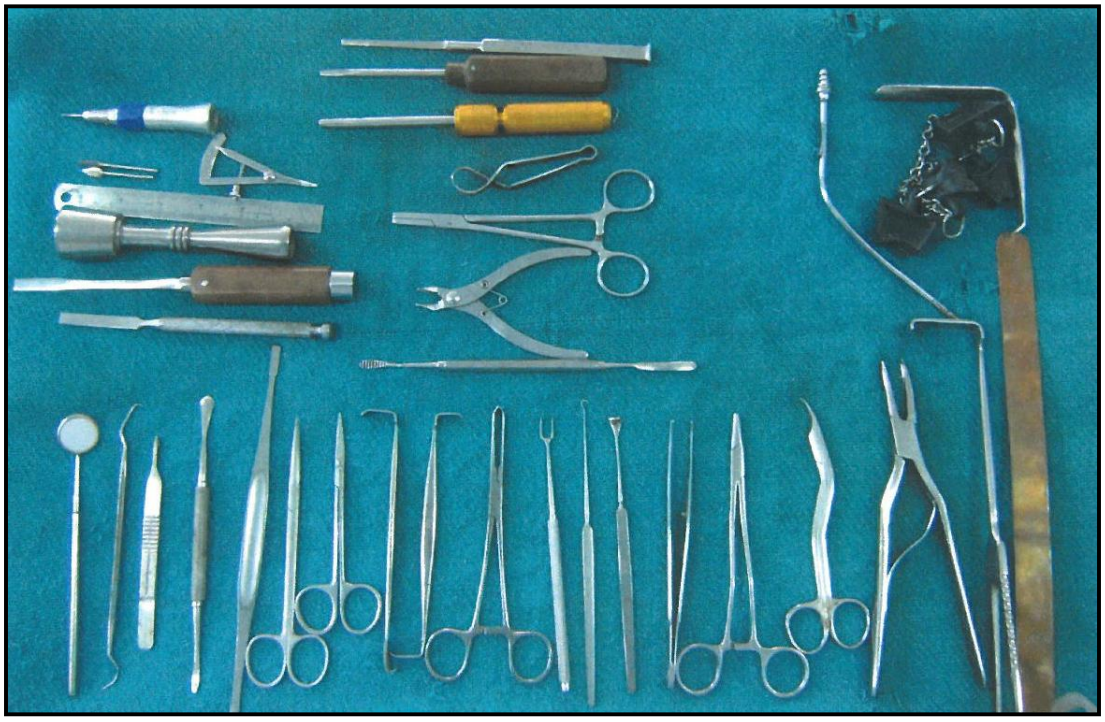
POST OPERATIVE CARE:

The patients were administered post-operative medications which included antibiotics, anti-inflammatory analgesics for a period of about 7 days to 10 days. They were also advised antibiotic eye drops and nasal decongestant for one week. Sutures were removed between the 8^{th} and 10^{th} post-operative day. All the patients were advised soft diet for about 3 weeks post operatively.

FOLLOW UP:

Clinical presence of diplopia, enopthalmos, restriction in ocular movement, were assessed once in a month post operatively. Patients were advised PNS view in the first post-operative month and CT scan in the third post-operative month. The patients were followed up for a period of 3 months to 6 months.

ARMAMENTARIUM



SURGICAL PROCEDURE

SURGICAL TECHNIQUE:

Preparation of the surgical site:

After naso endotracheal intubation, the surgical area was painted and draped. The orbital floor was approached through infra orbital or subciliary approach or pre-existing scar, whichever was applicable in all the cases.

Marking of the incision:

A temporary tarsoraphy was done using 4-0 silk. The incision was first marked using marking ink. The length of the incision was planned in accordance with the size of the defect and the fracture.

Local infiltration with vasoconstrictor:

Adrenaline with saline in a concentration of 1 in 1, 00,000 was used for vasoconstriction, injected subcutaneously in the surgical area.

Incision and dissection:

Incision was made using a No.15 Bard Parker blade. Dissection was done through the skin, subcutaneous tissues and the skin was dissected from the orbicularis oculi muscle for a few mm before splitting the muscle down to the orbital septum. The infra orbital nerve was identified and then retracted downwards to protect it. The muscle fibers were retracted to expose the periosteum.

Exposure of orbital floor:

The periosteum is incised 5-7mm below the infra orbital rim to prevent damage to the orbital septum and to avoid orbital fat herniation. As proposed by Rontal (1979), subperiosteal dissection is done within safe limits. The orbital floor is then explored and any orbital musculofascial entrapment and herniation is relieved. The floor defect is measured.

Reduction and fixation of associated fractures:

The associated zygomatico maxillary complex fractures in the patients were reduced through Dingman's approach and Gille's approach whichever is applicable and fixed with appropriate miniplates and screws.

Placement of mesh:

The mesh was cut according to the size of the defect and placed spanning the defect.

Closure:

Forced duction test was done to confirm passive movement of the eye ball with no mechanical restriction. Hemostasis was achieved. The stability of the mesh was checked and periosteum was closed with absorbable suture material (3-0 vicryl) to achieve tight closure to contain the mesh. Layer wise closure was done using absorbable suture material (3-0 vicryl) and non-absorbable suture material (4-0 prolene) for the skin. Tarsoraphy was released and dressing placed.

TARRSORAPHY

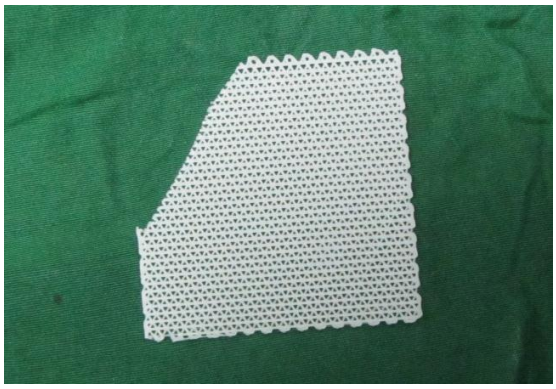
INCISION

DISSECTION

FRACTURE EXPOSED

FIXATION OF ASSOCIATED ZMC #

POLYCAPROLACTONE MESH



MESH IN PLACE

SUTURING

CASE REPORTS

CASE REPORT – 1

NAME: Mr. Sukumar

AGE/SEX: 23years/Male

CHIEF COMPLAINT:

Patient complains of pain in his facial region for the past three days

HISTORY OF PRESENTING ILLNESS:

History of self fall from bike after hitting a dog with his two wheeler and got injured by hitting stones by the roadside.

PAST MEDICAL HISTORY:

No relevant history

PAST SURGICAL HISTORY:

No relevant history

GENERAL EXAMINATION:

Patient is moderately built and nourished

Patient is conscious and coherent

No signs of pallor, icterus, cyanosis, clubbing, edema and regional lymphadenopathy.

LOCAL EXAMINATION:

EXTRA ORAL EXAMINATION:

Laceration in the left malar region.

Subconjuctival hemorrhage in the left eye.

Step deformity in the left infra orbital rim.

Step deformity in the left fronto-zygomatic suture region.

Paresthesia in the region supplied by the infra orbital nerve in the left side.

Increased inter canthal distance.

Depression of malar prominence on the left side.

INTRAORAL EXAMINATION:

Presence of tenderness in left zygomatic buttress region.

Occlusion is normal.

OPTHALMOLOGIC EXAMINATION:

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT	Full	Restricted
CONJUCTIVA	Clear	Subconjuctival hemorrhage
CORNEA	Clear	Clear
PUPIL	3mm RTL	3mm RTL
LENS	Clear	Clear
FUNDUS EXAMINATION	Normal	Normal
VISUAL ACUITY	6/6	6/6
DIPLOPIA	ABSENT	PRESENT
FORCED DUCTION TEST	NA	NA
INFRAORBITAL SENSATION	Intact	Diminished

INVESTIGATIONS:

PNS shows disruption of left infra orbital rim and fronto zygomatic suture separation.

CT scan with 3D reconstruction showed similar findings.

Volume:

Right orbit – 29.24cm^3

Left orbit – 34.12 cm^3

DIAGNOSIS :

Left Zygomatico Maxillary Complex fracture with orbital floor defect.

TREATMENT PLAN :

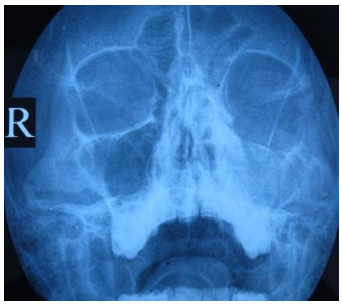
Open Reduction and Internal Fixation with orbital floor reconstruction using resorbable mesh.

PRE-OPERATIVE

Frontal view

Birds eye view

PNS view

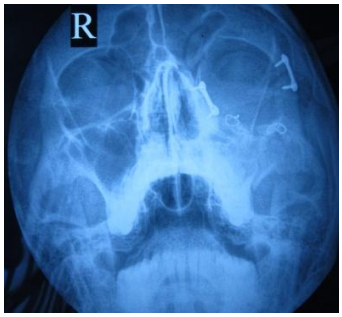


POST-OPERATIVE

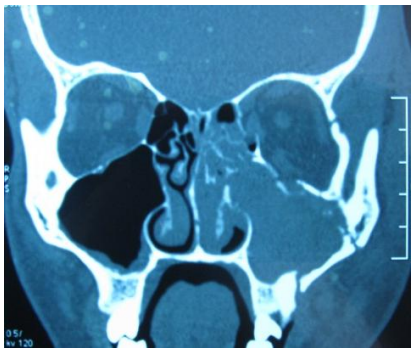
Frontal view

Birds eye view

PNS view

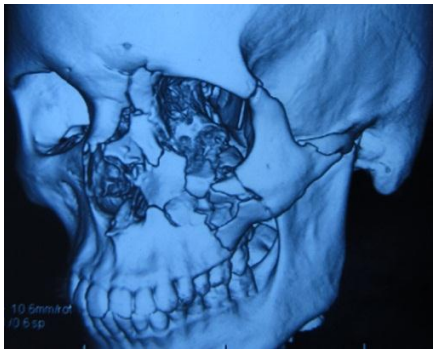


CT coronal section

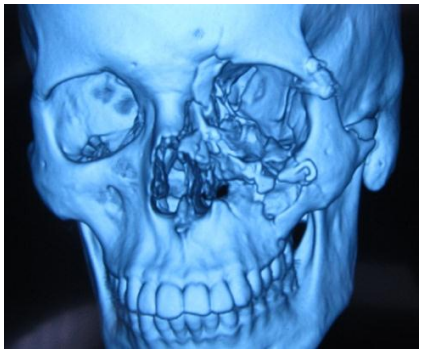


CT coronal section

CT 3D reconstruction



CT 3D reconstruction



CASE REPORT – 2

NAME: Mr. Nagooran

AGE/SEX: 42years/Male

CHIEF COMPLAINT:

Patient complains of pain in his facial region for the past four days.

HISTORY OF PRESENTING ILLNESS:

History of Road Traffic Accident – two wheeler vs two wheeler with the patient thrown on the roadside with his left side of his face hitting the ground.

PAST MEDICAL HISTORY:

No relevant history

PAST SURGICAL HISTORY:

No relevant history

GENERAL EXAMINATION:

Patient is moderately built and nourished

Patient is conscious and coherent

No signs of pallor, icterus, cyanosis, clubbing, edema and regional lymphadenopathy.

LOCAL EXAMINATION:

EXTRA ORAL EXAMINATION:

Abrasion wound above the left eyebrow.

Subconjuctival hemorrhage in the left eye.

Depressed malar prominence in the left side.

Step deformity in the left infra orbital rim.

Step deformity in the left fronto-zygomatic suture region.

Paresthesia in the region supplied by the infra orbital nerve in the left side.

INTRAORAL EXAMINATION:

Presence of tenderness in left zygomatic buttress region.

Occlusion is normal.

OPTHALMOLOGIC EXAMINATION

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT	Full	Full
CONJUCTIVA	Clear	Subconjuctival hemorrhage
CORNEA	Clear	Clear
PUPIL	3mm RTL	3mm RTL
LENS	Clear	Clear
FUNDUS EXAMINATION	Normal	Normal
VISUAL ACUITY	6/6	6/6
DIPLOPIA	ABSENT	ABSENT
FORCED DUCTION TEST	NA	NA
INFRAORBITAL SENSATION	Intact	Diminished

INVESTIGATIONS:

PNS shows disruption of left infra orbital rim and fronto zygomatic suture separation.

CT scan with 3D reconstruction showed similar findings.

Volume:

Right orbit – 28.31cm^3

Left orbit – 29.30 cm^3

DIAGNOSIS :

Left Zygomatico Maxillary Complex fracture with orbital floor defect.

TREATMENT PLAN :

Open Reduction and Internal Fixation with orbital floor reconstruction using resorbable mesh.

PRE-OPERATIVE

Frontal view

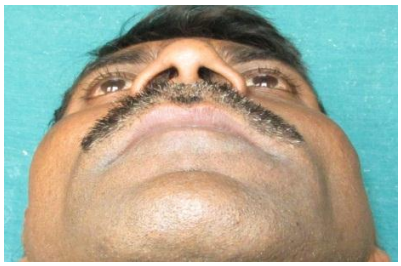
Worm's eye view

PNS view

POST-OPERATIVE

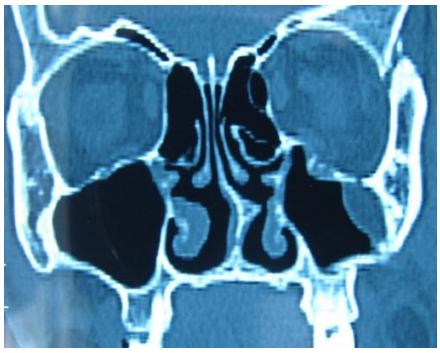
Frontal view

Worm's eye view

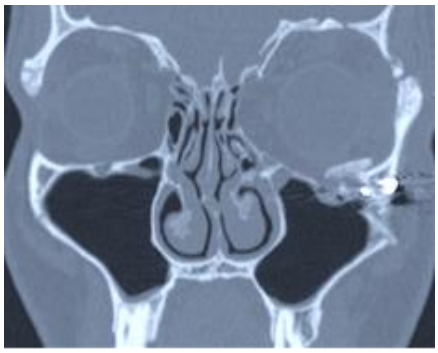


PNS view

CT coronal section

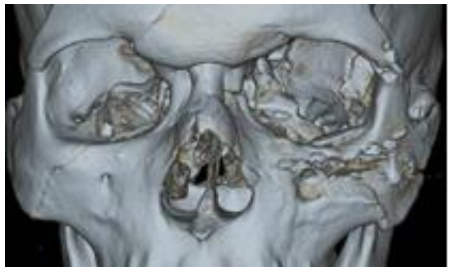


CT coronal section



CT 3D reconstruction

CT 3D reconstruction



CASE REPORT – 3

NAME: Mr. Raman

AGE/SEX: 53years/Male

CHIEF COMPLAINT:

Patient complains of pain in his facial region for the past one week.

HISTORY OF PRESENTING ILLNESS:

History of Road Traffic Accident – pedestrian vs auto with the patient thrown off and hitting the ground.

PAST MEDICAL HISTORY:

No relevant history

PAST SURGICAL HISTORY:

No relevant history

GENERAL EXAMINATION:

Patient is moderately built and nourished

Patient is conscious and coherent

No signs of pallor, icterus, cyanosis, clubbing, edema and regional lymphadenopathy.

LOCAL EXAMINATION:

EXTRA ORAL EXAMINATION:

Sutured wound in the right malar region.

Subconjuctival hemorrhage in the right eye.

Circumorbital ecchymosis around right eye.

Step deformity in the right infra orbital rim.

Step deformity in the right fronto-zygomatic suture region.

Paresthesia over the region supplied by the right infra orbital region.

INTRAORAL EXAMINATION:

Presence of tenderness in right zygomatic buttress region.

Occlusion is normal.

OPTHALMOLOGIC EXAMINATION

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT	Full	Full
CONJUCTIVA	Subconjuctival hemorrhage	Clear
CORNEA	Clear	Clear
PUPIL	3mm RTL	3mm RTL
LENS	Clear	Clear
FUNDUS EXAMINATION	Normal	Normal
VISUAL ACUITY	6/6	6/6
DIPLOPIA	ABSENT	ABSENT
FORCED DUCTION TEST	NA	NA
INFRAORBITAL SENSATION	Diminished	Intact

INVESTIGATIONS:

PNS shows disruption of right infra orbital rim and fronto zygomatic suture separation.

CT scan with 3D reconstruction showed similar findings.

Volume:

Right orbit – 28.65cm^3

Left orbit – 26.97 cm^3

DIAGNOSIS :

Right Zygomatico Maxillary Complex fracture with orbital floor defect.

TREATMENT PLAN :

Open Reduction and Internal Fixation with orbital floor reconstruction using resorbable mesh.

PRE-OPERATIVE

Frontal view

Birds eye view

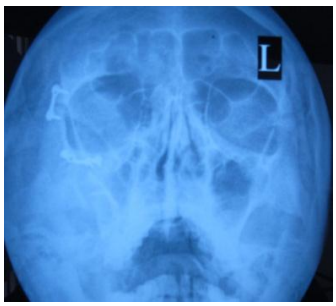
PNS view

POST-OPERATIVE

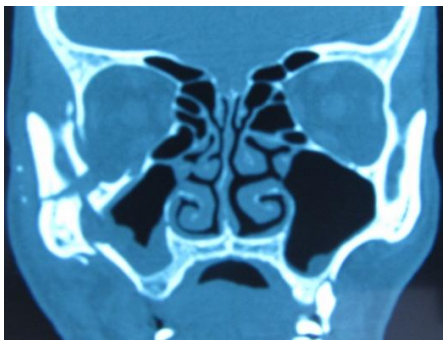
Frontal view

Birds eye view

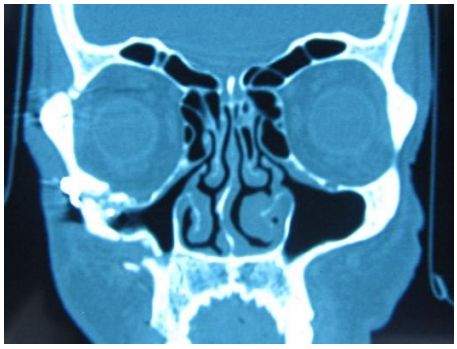
PNS view



CT coronal section

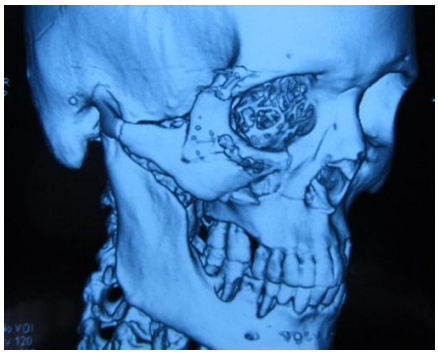


CT coronal section



CT 3D reconstruction

CT 3D reconstruction



CASE REPORT – 4

NAME: Mr. Satish

AGE/SEX: 26years/Male

CHIEF COMPLAINT:

Patient complains of pain in his facial region for the past one and half months.

HISTORY OF PRESENTING ILLNESS:

History of alleged Road Traffic Accident two wheeler vs four wheeler.

PAST MEDICAL HISTORY:

No relevant history

PAST SURGICAL HISTORY:

No relevant history

GENERAL EXAMINATION:

Patient is moderately built and nourished

Patient is conscious and coherent

No signs of pallor, icterus, cyanosis, clubbing, edema and regional lymphadenopathy.

LOCAL EXAMINATION:

EXTRA ORAL EXAMINATION:

Depression of malar prominence on the right side.

Supra tarsal hooding present in the right side.

Healed sutured wound in the right eyebrow region.

Step deformity in the right infra orbital rim.

Step deformity in the right fronto-zygomatic suture region.

INTRAORAL EXAMINATION:

Presence of tenderness in right zygomatic buttress region.

Occlusion is normal.

OPTHALMOLOGIC EXAMINATION

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT	Full	Full
CONJUCTIVA	Clear	Clear
CORNEA	Clear	Clear
PUPIL	3mm RTL	3mm RTL
LENS	Clear	Clear
FUNDUS EXAMINATION	Normal	Normal
VISUAL ACUITY	6/6	6/6
DIPLOPIA	ABSENT	ABSENT
FORCED DUCTION TEST	NA	NA
INFRAORBITAL SENSATION	Intact	Intact

INVESTIGATIONS:

PNS shows disruption of right infra orbital rim and fronto zygomatic suture separation.

CT scan with 3D reconstruction showed similar findings.

Volume:

Right orbit – 33.83 cm^3

Left orbit – 28.14cm^3

DIAGNOSIS :

Right Zygomatico Maxillary Complex fracture with orbital floor defect.

TREATMENT PLAN :

Open Reduction and Internal Fixation with orbital floor reconstruction using resorbable mesh.

PRE-OPERATIVE

Frontal view

Birds eye view

PNS view

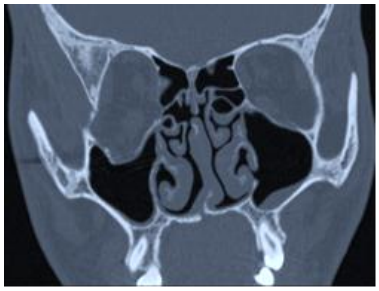
POST-OPERATIVE

Frontal view

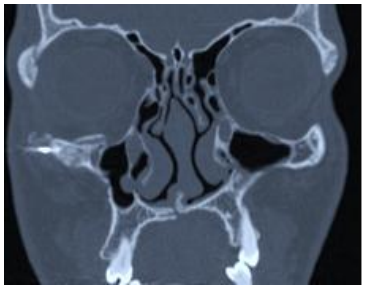
Birds eye view

PNS view

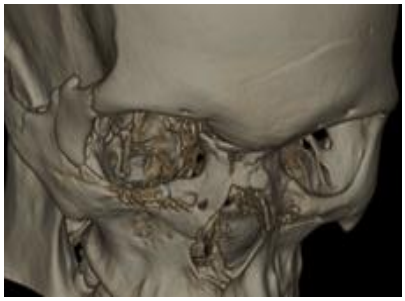
CT coronal section



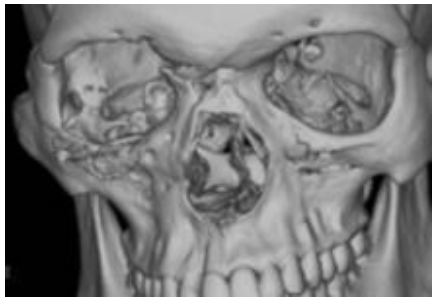
CT coronal section



CT 3D reconstruction



CT 3D reconstruction



CASE REPORT – 5

NAME: Mr. Peer Mohammed

AGE/SEX: 29years/Male

CHIEF COMPLAINT:

Patient complains of pain in his facial region for the past two months.

HISTORY OF PRESENTING ILLNESS:

History of assault with the patient being hit by six persons with wooden logs and rods.

PAST MEDICAL HISTORY:

No relevant history

PAST SURGICAL HISTORY:

No relevant history

GENERAL EXAMINATION:

Patient is moderately built and nourished

Patient is conscious and coherent

No signs of pallor, icterus, cyanosis, clubbing, edema and regional lymphadenopathy.

LOCAL EXAMINATION:

EXTRA ORAL EXAMINATION:

Depressed malar prominence on the right side.

Restricted mouth opening.

Supra tarsal hooding of the right eye present.

Step deformity in the right infra orbital rim.

Step deformity in the right fronto-zygomatic suture region.

INTRAORAL EXAMINATION:

Occlusion is normal.

OPTHALMOLOGIC EXAMINATION

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT	Full	Full
CONJUCTIVA	Clear	Clear
CORNEA	Clear	Clear
PUPIL	3mm RTL	3mm RTL
LENS	Clear	Clear
FUNDUS EXAMINATION	Normal	Normal
VISUAL ACUITY	6/6	6/6
DIPLOPIA	ABSENT	ABSENT
FORCED DUCTION TEST	NA	NA
INFRAORBITAL SENSATION	Intact	Intact

INVESTIGATIONS:

PNS shows disruption of right infra orbital rim and fronto zygomatic suture separation.

CT scan with 3D reconstruction showed similar findings.

Volume:

Right orbit – 34.85 cm^3

Left orbit – 27.86 cm^3

DIAGNOSIS :

Right Zygomatico Maxillary Complex fracture with orbital floor defect.

TREATMENT PLAN :

Open Reduction and Internal Fixation with orbital floor reconstruction using resorbable mesh.

PRE-OPERATIVE

Frontal view

Birds eye view

PNS view

POST-OPERATIVE

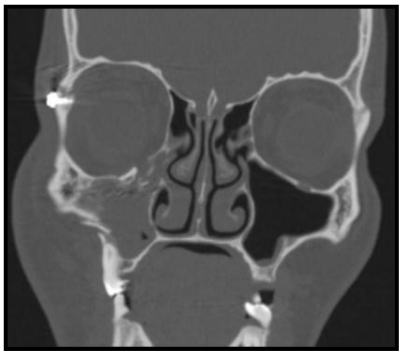
Frontal view

Birds eye view

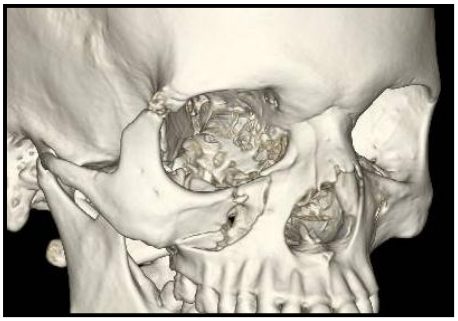
PNS view

CT coronal section

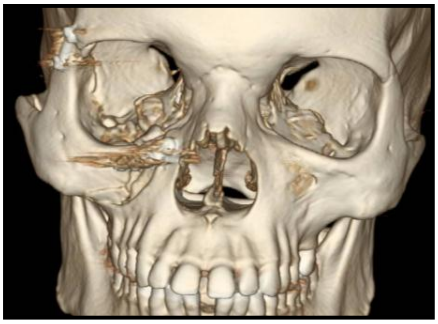
CT coronal section



CT 3D reconstruction



CT 3D reconstruction



CASE REPORT – 6

NAME: Mr. Selvam

AGE/SEX: 23years/Male

CHIEF COMPLAINT:

Patient complains of pain in his facial region for the past ten days

HISTORY OF PRESENTING ILLNESS:

History of self fall from bike after hitting a dog with his two wheeler and got injured by hitting stones by the roadside.

PAST MEDICAL HISTORY:

No relevant history

PAST SURGICAL HISTORY:

No relevant history

GENERAL EXAMINATION:

Patient is moderately built and nourished

Patient is conscious and coherent

No signs of pallor, icterus, cyanosis, clubbing, edema and regional lymphadenopathy.

LOCAL EXAMINATION:

EXTRA ORAL EXAMINATION:

Depressed malar prominence on the left side.

Subconjuctival hemorrhage in the left eye.

Step deformity in the left infra orbital rim.

Step deformity in the left fronto-zygomatic suture region.

Paresthesia in the region supplied by the infra orbital nerve in the left side.

INTRAORAL EXAMINATION:

Presence of tenderness in left zygomatic buttress region.

Occlusion is normal.

OPTHALMOLOGIC EXAMINATION

PARAMETERS	**RIGHT EYE**	**LEFT EYE**
OCULAR MOVEMENT	Full	Restricted
CONJUCTIVA	Clear	Subconjuctival hemorrhage
CORNEA	Clear	Clear
PUPIL	3mm RTL	3mm RTL
LENS	Clear	Clear
FUNDUS EXAMINATION	Normal	Normal
VISUAL ACUITY	6/6	6/6
DIPLOPIA	ABSENT	PRESENT
FORCED DUCTION TEST	NA	NA
INFRAORBITAL SENSATION	Intact	Diminished

INVESTIGATIONS:

PNS shows disruption of left infra orbital rim and fronto zygomatic suture separation.

CT scan with 3D reconstruction showed similar findings.

Volume:

Right orbit – 27.86 cm^3

Left orbit – 30.48 cm^3

DIAGNOSIS :

Left Zygomatico Maxillary Complex fracture with orbital floor defect.

TREATMENT PLAN :

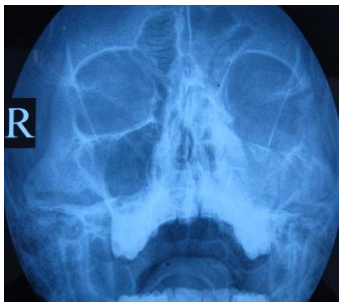
Open Reduction and Internal Fixation with orbital floor reconstruction using resorbable mesh.

PRE-OPERATIVE

Frontal view

Birds eye view

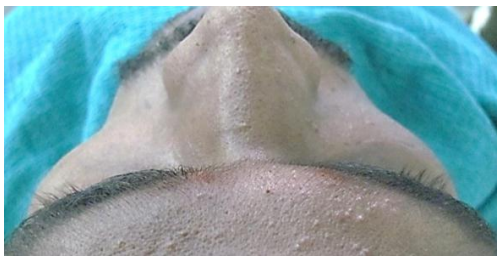
PNS view



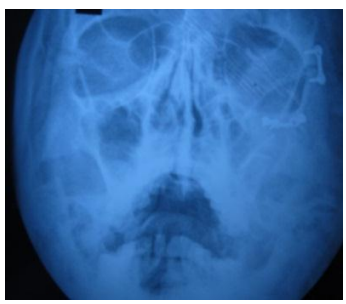
POST-OPERATIVE

Frontal view

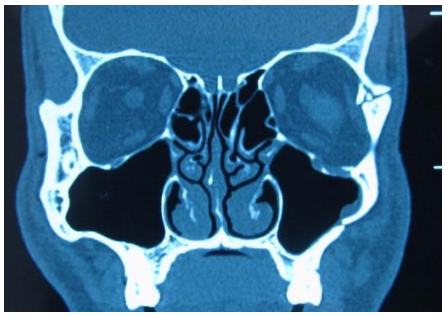
Birds eye view



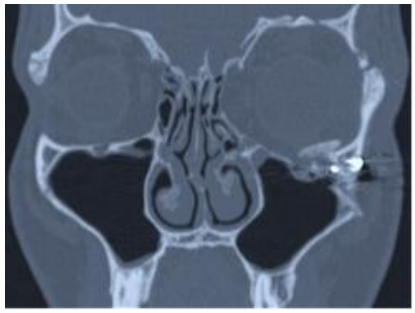
PNS view



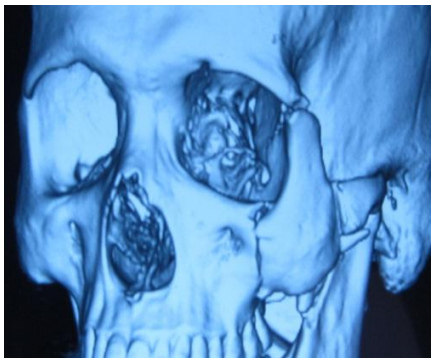
CT coronal section



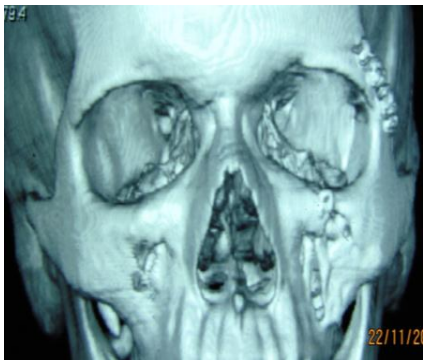
CT coronal section



CT 3D reconstruction



CT 3D reconstruction



OBSERVATION & RESULTS

OBSERVATION AND RESULTS

A total of six patients who had undergone orbital floor reconstruction at Tamil Nadu Govt. Dental College & Hospital were analyzed. All the patients had impure blow out fracture of the orbital floor with associated zygomatico maxillary complex fractures.

All the patients in the study were men and the age range was between 23 years to 53 years. Four patients were injured because of road traffic accidents, while in the rest of the two patients, the cause was interpersonal violence. Two patients were treated after two months of trauma and four cases were treated in the second to third weeks of fracture.

PREOPERATIVE CLINICAL FEATURES:

The initial clinical presentation of the patients varied. Out of the six patients, two patients presented with diplopia. All the six patients had varied degrees of enopthalmos and in two patients, restriction of ocular movement was present.

POST OPERATIVE ASSESSMENT:

The follow up assessments were performed between three to six months post operatively, calculated from the date of treatment. The post-operative outcome was assessed for clinical diplopia status, wound infection, dehiscence, graft rejection or extrusion, post-operative extra ocular movements, enopthalmos and presence of ectropion or entropion. Only one patient had ectropion which resoled in three weeks post operatively.

Clinical diplopia status:

Out of the six patients, two patients had diplopia preoperatively. Diplopia resolved in all the two patients post operatively.

Wound infection or dehiscence:

Wound healing in all the six patients were satisfactory. There were no signs of infection at the surgical site.

Graft rejection or extrusion:

There were no signs or symptoms of mesh rejection in all the six patients in the follow up period of three months to six months.

Post-operative extraocular movements:

Two patients out of the six had limitation of extra ocular movement. Post operatively the limitation of movement resolved.

Correction of enopthalmos:

Post operatively, CT scan was taken and volume assessment was done using Volume Share II, an installed application. Restoration of volume to the comparative contralateral side was achieved in only one patient. In the rest of the five patients, total correction of enopthalmos to the desired extent was not achieved. Though volume assessment showed lack of correction, the overall appearance of the patient had improved after floor correction and reduction of fragments.

PRE-OPERATIVE FINDINGS

S.NO	PATIENT NAME	AGE/SEX	DIPLOPIA	EYEBALL RESTRICTION	INFRA ORBITALNERVE INVOLVEMNT	VISUAL ACUITY	ENOPTHALMOS
1.	SUKUMAR	23/M	PRESENT	PRESENT	PRESENT	6/6	PRESENT
2.	NAGOORAN	42/M	ABSENT	ABSENT	PRESENT	6/6	PRESENT
3.	RAMAN	53/M	ABSENT	ABSENT	PRESENT	6/6	PRESENT
4.	SATISH	26/M	ABSENT	ABSENT	ABSENT	6/6	PRESENT
5.	PEER MOHD	29/M	ABSENT	ABSENT	ABSENT	6/6	PRESENT
6.	SELVAM	35/M	ABSENT	PRESENT	PRESENT	6/6	PRESENT

POST-OPERATIVE FINDINGS

S.NO	PATIENT NAME	AGE/SEX	DIPLOPIA	EYEBALL RESTRICTION	INFRA ORBITALNERVE INVOLVEMNT	VISUAL ACUITY	ENOPTHALMOS
1.	SUKUMAR	23/M	ABSENT	ABSENT	ABSENT	6/6	PRESENT
2.	NAGOORAN	42/M	ABSENT	ABSENT	ABSENT	6/6	ABSENT
3.	RAMAN	53/M	ABSENT	ABSENT	PRESENT	6/6	PRESENT
4.	SATISH	26/M	ABSENT	ABSENT	PRESENT	6/6	PRESENT
5.	PEER MOHD	29/M	ABSENT	ABSENT	ABSENT	6/6	PRESENT
6.	SELAM	35/M	ABSENT	ABSENT	ABSENT	6/6	PRESENT

CT BASED VOLUME ASSESSMENT

S.NO	PATIENT NAME	AGE/SEX	VOLUME OF UNAFFECTED ORBIT c.cm	AFFECTED ORBIT PRE-OP VOLUME c.cm	AFFECTED ORBIT POST-OP VOLUME c.cm	CORRECTION ACHEIVED c.cm
1.	SUKUMAR	23/M	29.24	34.12	33.87	0.25
2.	NAGOORAN	42/M	28.31	29.30	28.24	1.06
3.	RAMAN	53/M	26.97	28.65	27.92	0.73
4.	SATISH	26/M	28.14	33.83	32.74	1.09
5.	PEER MOHD	29/M	27.86	34.85	34.01	0.84
6.	SELVAM	35/M	27.78	30.48	29.18	1.03

DISCUSSION

DISCUSSION

The orbital walls, being very thin, especially in the floor and medial walls are easily damaged by rising intraorbital pressure, with subsequent enopthalmos as one of the most common problems. Classical symptoms of orbital fracture are enopthalmos, hypopthalmos, and diplopia, due to increased orbital volume, injury and periorbital soft tissue displacement[26.] Enopthalmos in blowout fracture is attributed to several causes: loss of ligament and bone support for the globe and orbital fat atrophy or fat loss and herniation of fat in the floor fracture. Diplopia is caused due to the alteration in globe level[29].

Management of orbital fractures, whether pure blowout fractures or with associated zygomatic complex fractures, is a challenging problem for the oral and maxillofacial surgeon. Their reconstruction requires 1) release of entrapped orbital floor muscle, 2) reduction of the fractured floor, 3) reduction of the floor defect, 4) prevention of infection from the antrum, 5) return of physiologic function of the extraocular muscles, 6) elevation of the depressed zygoma and 7) correction of volume discrepancy between the orbits[39].

Technically, correction of hypoglobus is easier than enopthalmos, because correction of enopthalmos demands a wide, deep subperiosteal dissection and positioning of the implant material posterior to the equator of the globe, during which the inherent risk of injury to the apex of the orbit should be avoided[36].

Discussion is still ongoing regarding the choice of material for reconstruction and filling – in the defect of the orbital floor, especially that various autogenous and synthetic materials have been introduced for this reconstruction. The material used for orbital wall reconstruction should be readily available, easy to mold, easy to anchor,

should be biocompatible and non-carcinogenic. If the material is resorbable, it should be osteogenic, osteoconductive or osteoinductive[4]. The choice of a particular material for reconstruction is dependent on various factors like surgical access, the size of the orbital floor defect, presence of enopthalmos and the surgeon's experience.

Various factors influence the choice of material for use in orbital floor reconstruction. The choice depends on the size of the defect, involvement of multiple walls, adaptation to internal contours, restoration of proper volume, presence of adjacent sinus cavity, prevention of displacement, risk of further trauma, adhesions or restriction of ocular motility, and early versus later repair[50].

Autogenous bone grafts remain one of the materials preferred widely for the reconstruction of severely disrupted orbital floors. These can be harvested from various sites including calvarium, antrum, mandibular symphysis, ramus of the mandible, iliac crest, rib etc. Although bone grafts are excellent sources for reconstruction of floor of the orbit, they are difficult to shape and also undergo a undetermined rate of resorption and so there is a potential for late occurring enopthalmos[60]. Other disadvantages associated with their use are donor site morbidity, increased operative time, and quantity is limited[50]. Autogenous cartilage grafts have also been used because of their ease in harvesting, and fitting to contour because of their malleable structure[60].

ILANKOVAN AND JACKSON (1992) stated that cartilage in its fresh state has the tendency to warp and therefore is unsatisfactory for use in orbital reconstruction. Other authors have also stated the disadvantage of cartilage that it has the tendency to warp. One more disadvantage with the use of cartilage as grafts for orbital wall reconstruction is that when carved for the purpose of recontouring to fit to the internal

contours, the cartilage undergoes changes in the balance of intrinsic tensile and expansile forces causing distortion of cartilage shape. This can lead to late complications because the changes in the shape of the graft can alter the support and volume within the orbit[20].

The other choice for orbital floor reconstruction is the use of allogeneic materials. **WAITE AND CLANTONS** (1988) have reported that these grafts give successful results as reconstruction materials[76]. The main concern with regard to the use of allogeneic materials is the antigenicity of the material and transmission of infectious diseases. Delayed hypersensitivity reactions have also been reported with the use of xenografts. Despite being careful on the sterilization techniques, risk of infectious disease transmission is the main disadvantage of using allogeneic materials[50].

Because of the various shortcomings associated with autogenous bone grafts, alloplastic materials have been gaining popularity for use in orbital reconstruction. Even though non resorbable materials carry many advantages, they have many drawbacks including risk of extrusion and infection, risk of injuries to the tissues of the orbital apex. Removal of these materials in case of such complications may be extremely difficult because of fibrous ingrowth and also the possibility of osseous overgrowth or osseous integration of the material[50].

The idea behind using resorbable mesh is that an ideal implant for orbital floor reconstruction is the one that is present long enough to establish a supportive structure for the periorbita and is then resorbed by the body.

HOLLIER et al (2001) conducted a study in which 12 orbital floor fractures were treated with a resorbable (Lactosorb) 0.25mm sheet out of which, only one patient

developed delayed foreign body reaction which necessitated removal of the excessive portion of the mesh and securing with absorbable screw at the infra orbital margin[29].

PERSONS B et al (2002) stated successful use of 25 x 25mm 0.65mm thick resorbable perforated plate through a trans oral endoscopic approach in five patients. According to their study, none of the patients developed enopthalmos or infection during the follow up period of 3months to twelve months[45].

SERHAN TUNCER et al (2007) did restoration of orbital floor by using resorbable mesh in seventeen patients. In all the cases, there was no evidence of infection. They stated anterior displacement of the mesh causing ectropion in one patient which required re-operation. In one case, delayed foreign body reaction related to infra orbital rim plate required debridement. There was no case of migration, extrusion or protrusion of implant. None of their patients required a second operation for removal of implant[60].

In our study, we have used resorbable plates made of polycaprolactone [Osteomesh].

Poly-e-caprolactone (PCL) is one of the aliphatic polyesters[49,59] and is highly biocompatible with osteoblasts[17]. In vivo degradation of PCL begins with random hydrolytic chain scission of the ester linkages, manifested by a reduction in the viscosity and molecular weight of the polymer. The second phase of polymer degradation is characterized by a decrease in the rate of chain scission and the onset of weight loss, implant fragmentation and intracellular degradation. The biomechanical strength of the implant after three months *in vivo* in animal study demonstrated stiffness of 60% of normal bone. [16.]

Low SW et al (2009) in their study used Osteoplug™ for covering bur holes created in the cranium during neurosurgical procedures. They found that PCL did not interfere with imaging techniques and the slow degrading PCL framework allowed neovascularization to seed for wound healing. The material was found to be biocompatible, capable of facilitating revascularization, osteoinductive and osteoconductive[23]. By two years, the process provided a stable integration of graft material into the bone tissues. The slow-degrading PCL framework allows neovascularization to seed for wound healing[35].

Throughout the course of follow up, the mesh was tolerated well, with none of the patients developing adverse reactions to the material like pain, scarring, sinus infections, or excessive debris production. No other implant related complications were observed. Diplopia and restriction of eyeball mobility were corrected. There was no evidence of extrusion of the implant or implant migration. Correction of enopthalmos was achieved to the desirable extent in only one case and in the rest of the cases, enopthalmos was not corrected in comparison to the unaffected orbit though the esthetic results were good. The ease of handling of the resorbable (caprolactone) mesh [Osteomesh] allows contouring for accurate reconstruction of the internal orbit.

Considering all the observations in our study, resorbable (polycaprolactone) mesh [Osteomesh] can be used as a suitable implant for orbital floor reconstruction. The clinical outcome is comparable, or even better, to other biodegradable alloplastic materials.

SUMMARY

&

CONCLUSION

SUMMARY AND CONCLUSION

Fracture of the orbital floor causes herniation of the orbital contents into the maxillary sinus. This safety mechanism to prevent perforation of the globe often leads to the condition termed enopthalmos, which is basically due to the discrepancy between the volume of the orbital cavity and the volume of the orbital contents. Apart from this, orbital floor fracture also may cause diplopia, extra ocular muscle entrapment and restriction of eyeball mobility. Surgical intervention with reconstruction of the fractured orbital floor defect is necessary.

In our study, six patients who reported to the Department of Oral and Maxillofacial Surgery, Tamil Nadu Govt. Dental college and Hospital, Chennai with impure blow out fracture of the orbital floor with associated zygomatico maxillary complex fractures were assessed and taken up for surgery. Reconstruction of the orbital floor defect with resorbable (polycaprolactone) mesh [Osteomesh] was done along with reduction and fixation of the associated zygomatico maxillary complex fracture.

The consequences of the orbital floor fractures namely diplopia, restriction in eyeball mobility was corrected in all the patients in which these findings were present. None of the patients had evidence of infection or extrusion of the implant from the surgical site. Post-operative ophthalmologic examination also revealed normal findings. Correction of enopthalmos in relation to the unaffected site could not be achieved satisfactorily. This could be related to the reason that three of the patients had a comminuted fracture and two of them reported after two months of trauma. Both these conditions could have caused loss or herniation of fat which is very difficult to restore.

Based on the results of our six cases, we conclude that resorbable (polycaprolactone) resorbable mesh [Osteomesh] has been found to be a very useful material for orbital floor reconstruction.

The follow up period has to be increased to further authenticate its use for floor reconstruction.

A further study of increased study sample and increased period of observation would prove to be valuable.

BIBLIOGRAPHY

BIBLIOGRAPHY

1.A.C.Hundepool, M.A.P Willemsen, M.J. Koudstaal. Open reduction versus endoscopically controlled reconstruction of orbital floor fractures: A retrospective analysis. Int.J.Oral Maxillofac. Surg. 2012;41:489-93.

2.Anderson PJ, Poole MD. Orbital floor fractures in young children. Journal of Cranio Maxillo-facial Surgery. 1995 ; 23:151-4.

3.Al-Suhum J, Lindqvist C. A comparative study of two implants used to repair inferior orbital wall bony defects; autogenous bone grafts vs bioresorbable Poly-L/DL-Lactide [P(L/DL)LA 70/30] plate. J Oral Maillofac. Surg.2006; 64:1038-48.

4.Amrani S, Anastasso GE, Montazem AH. Mandibular ramus/coronoid process grafts in maxillofacial reconstructive surgery. J Oral Maillofac. Surg.2010;68:641-46.

5.Andre Montazem, David v Valauri, Hugo St-Hilare. The mandibular symphysis as a donor site in maxillofacial bone grafts: A quantitative anatomic study. J Oral Maillofac. Surg. 2000; 58:1368-71.

6.Angela P Rake, Scott A Rake, James Q Swift, Warren Schubert. A single reformatted oblique sagittal view as an adjunct to coronal CT for the evaluation of orbital floor fracture. J Oral Maillofac. Surg.2004; 62:456-59.

7.Antonyshyn O, Gruss JS, Galbraith DJ, Hurwitz JJ. Complex orbital fracture: A critical analysis of immediate bone graft reconstruction. Annals of Plastic Surgery 1989;22:220.

8.Asamura S, Ikada Y, Matsunaga k, Wada M, Nisogai N. Treatment of orbital floor fracture using a periosteum polymer complex. Journal of Cranio Maxillo-facial Surgery 2010;48:617-20.

9.Bayat M, Momen-Heravi, Khalilzadeh O, Mirhosseni Z, Sadeghi – Tari. A Comparison of conchal cartilage graft with nasal septal cartilage graft for reconstruction of orbital floor blow out fractures. British Journal of Oral and Maxillofacial Surgery 2010;48: 617-620.

10.Bilen BT, Kilinc H, Arslan A, Aslan S. Reconstruction of orbital floor and maxilla with divided vascularized calvarial bone flap in one session. Journal of Plastic Reconstructive and esthetic Surgery 2006;59:1305-11.

11.Converse J, Smith B. Blow out fracture of the floor of the orbit. Trans Am Acad Opthalmol Otolaryngol 1960;64:676-88.

12.Damir B Mattic, Raymond Tse, Avik Bannerjee, Cory C Moore. Rounding of the inferior rectus muscle as a predictor of enopthalmos in orbital floor fractures. Journal of Craniofacial Surgery 2007;18.

13.Dongmei He, Prestom Blomquist Edward Ellis. Association between ocular injuries and internal orbit fractures. J Oral Maillofac. Surg. 2007;65:713-20.

14.Dutton G N., Al-Quraini. Opthalmic consequences of maxillofacial injuries. In R.J.Fonseca and R. V. Walker (Eds), Oral and Maxillofacial Trauma, vol.1, 1st Ed. Philadelphia; Saunders, 1991 Pg. 543-72.

15.Gonzalez MO, Durairaj VD. Indirect orbital floor fracture; A meta-analysis. Middle East African Journal of Opthalmology 2010;17:138-41.

16.Gungormus M, Yavuz MS. The ascending ramus of the mandible as a donor site in maxillofacial bone grafting. J Oral Maillofac. Surg. 2002;60:1316-18.

17.Gurav N, Downes S. A qualitative in vitro evaluation of the degradable materials poly(caprolactone), poly(hydroxybutyrate) and a poly(hydroxybutyrate-hydroxyvalerate)copolymer. J Mater Sci: Mater Med 1994;5:784-7.

18.Harris GJ, Garcia GH, Logani SC, Murphy ML, Sheth BP, Seth AK. Orbital blow out fractures: correlation of post-operative computed tomography and post-operative ocular motility. Trans Am Opthalmol. Society 1998; 96:329-53.

19.Iizuka T, Mikkonen P, Paukku P. Reconstruction of orbital floor with polydiaxonone plate. Int.J.Oral Maxillofac. Surg.1991;20:83.

20.Ilankovan V, Jackson IT. Experience in the use of calvarial bone grafts in orbital floor reconstruction. British Journal of Oral and Maxillofacial Surgery 1992;30:92.

21.Jank S, Emshoff R, Schuchter B, Strobl H, Brandlmaier I, Norer B. Orbital reconstruction with flexible Ethisorb patches; A retrospective long-term follow-up study. Oral Surgery Oral Medicine Oral Path Oral Radiology and Endodontics 2003; 95:16-22.

22.Jehad Al-Sukhun, Christian Lindqvist. A comparative study of 2 implants used to repair inferior orbital wall bony defects: Autogenous bone grafts vs bioresorbable poly-L/DL Lactide [P(L/DL)LA 70/30] plate. J Oral Maillofac. Surg. 2006;64:1038-48.

23.Juan Pena TC, Isabel Izquierdo Barba, Antonio l Doadico Maria Vallet Regi. Long term degradation of poly [(epsilon)-caprolactone] films in biologically related fluids. Polymer Degradation and Stability 2006;91:1424-32.

24.Kalk WWI, Raghoebar GM, Jansma J, Boering G. Morbidity from iliac crest bone harvesting. J Oral Maillofac. Surg. 1996;54:1424-9.

25.Kessler P, Thowarth M Bloch-Birkholz A, Nkenke E, Neukam FW. Harvesting of bone from the iliac crest – comparison of anterior and posterior sites. British Journal of Oral and Maxillofacial Surgery 2005;43:51-56.

26.Kontio RK, Laine P, Salo A, Paukku P, Lindqvist C, Suuronen R. Reconstruction of internal orbital wall fracture with iliac crest free bone graft: clinical, computed tomography and magnetic resonance imaging follow-up study. Plastic Reconstructive surgery. 2006;118:1365-74.

27.Kosaka M, Matsuzava Y, Mori H, Matsunaga K, Kamiishi H. Orbital wall reconstruction with bone grafts from the outer cortex of the mandible. Journal of Cranio Maxillo-facial Surgery 2004;32:374-80.

28.Kun Hwang, Dong Hyun Kim. Comparison of the supporting strength of a Poly-L-Lactic Acid sheet and porous polyethylene (Medpor) for the reconstruction of orbital floor fractures. Journal of Craniofacial Surgery 2010;21:847-53.

29.Larry H Hollier, Nicole Rogers, Edward Berzin, Samuel Stal. Resorbable mesh in the treatment of orbital floor fractures. The Journal of Craniofacial Surgery 2001;12:242-6.

30.Lawrence Tong, Richard J Bauer, Steven R Buchmax. A current 10 year retrospective survey of 199 surgically treated orbital floor fracture in a non-urban testing care center. Plastic Reconstructive Surgery 2001;108:612.

31.Lee HH, Alcaraz N, Reino A, Lason W. Reconstruction of orbital floor fractures with maxillary bone. Arch Otolaryngol Head NeckSurgery 1998;124:56-9.

32.Lee JW, Chiu HY. Quantitative Computed Tomography for evaluation of orbital volume change in blow out fractures. J Formos Med Assoc, 1993;92:349-55.

33.Leon A Assel, Daid M Feinerman. Lag screw technique for orbital floor reconstruction with autologous bone grafts. J Oral Maillofac. Surg.1994;52:646-7.

34.Lew D. Orbital floor reconstruction with autogenous mandibular symphyseal bone grafts. J Oral Maillofac. Surg.1997;55:330-2.

35.Low S W, Ng Y J, Yeo T T, Chou N. Use of Osteoplug^{TM} polycaprolactone implants as novel burr-hole covers. Singapore Med Journal 2009; 50 : 777-80.

36.Manson P. N, Clifford C M, Su C T, Illif N , Morgan R. Mechanisms of global support and post traumatic enopthalmos: I. The anatomy of the ligaments ling and its relation to intramuscular cone orbital fat. Plast. Reconstr. Surg. 1986; 77;193.

37.Masaaki Kosaka, Yusuke Matsuza WA, Hiromasa Mori, Kazuhide Matsunga. Orbital wall reconstruction with bone grafts from the outer cortex of the mandible. Journal of Cranio Maxillo-facial Surgery 2004;374-80.

38.Matthias Gierloff, Niels Gunnar Karl Seeck, Ingo Springer, StephanThomas Becker, Christian Kandzia, Jorg Wiltfang. Orbital floor reconstruction with resorbable

Polydioxanone implants. Journal of Craniofacial Surgery 2012;23: 161-4.

39.Mintz SM, Ettinger A, Schmakel T, Gleason MJ. Contralateral coronoid process bone grafts for orbital floor reconstruction: An anatomic and clinical study. J Oral Maillofac. Surg. 1998;56:1140-44.

40.Montazem A, Valauri DV, St-Hilare H, Buchbinder D. The mandibular symphysis as a donor site in maxillofacial bone grafting: A quantitative anatomic study. J Oral Maillofac. Surg. 2000;58:1368-71.

41.Mustarde cited in Luigi Clauser, Manlio Galie, Francesso Pagliaro, Riccardo. Post traumatic enopthalmos : Etiology, Principles of Reconstruction, and Correction. Journal of Craniofacial Surgery 2008; 19.

42.Nicholas A Drage, Vaseekaran Sivarajasingam B. The use of cone beam computed tomography in the management of isolated orbital floor fractures. British Journal of Oral and Maxillofacial Surgery 2009;47:65-6.

42.Nicholas A. Drage, Vaseekaran Sivarajasingam. The use of cone beam computed tomography in the management of isolated orbital floor fractures. British Journal of Oral and Maxillofacial Surgery 2009;47: 65–66.

43.Noah A Sandler, Ricardo L Carrau, Mark W Archer. The use of maxillary sinus endoscopy in the diagnosis of orbital floor fracture. J Oral Maillofac. Surg. 1999;57:399-403.

44.Pascal Buchel, Akram Rahal, Ichiro Seto, Tateyuki Ilizuka. Reconstruction of orbital floor fracture with polyglactin 910/polydiaxonon patch (Ethisorb): A retrospective study. J Oral Maillofac. Surg. 2005;63:646-50.

45.Persons B L, Wong GB. Transoral endoscopic orbital floor repair using resorbable plates. Journal of Craniofacial Surgery 2002;13:483.

46.Peter Ward Booth, Barry L Eppley, Rainer Schmelzeisen. Maxillofacial Trauma and Esthetic Facial Reconstruction; Elsevier: Reprint 2004.

47.Philip D. Darney, Scott E.Monroe, Cynthia M. Klaisle, Ana Alvarado. Clinical evaluation of the Capronor contraceptive implant: Preliminary report. American Journal of Obstetrics & Gynecology 1989;160:1292-95

48.Pier Luigi Grenga, Gabriele Reale, Carmela Cofone, Alessandro Meduri, Piero Ceruti, Roberto Grenga. Hess area ratio and diplopia: Evaluation of 30 patients undergoing surgical repair for orbital blow-out fracture. Ophthal Plast Reconstr Surg, 2009;25:123-25.

49.Pitt CG, Chasalow FI, Hibionada YM, Klimas DM, Schindler A. Aliphatic polyesters. I. The degradation of poly(e-caprolactone) in vivo. J Appl Polym Sci 1981;26:3779-87.

50.Potter J K, Ellis E. Biomaterials for reconstruction of the internal orbit. J Oral Maillofac. Surg. 2004;62:1280-97.

51.Ramieri G, MC Spada, SD Bianchi, S Berrone. Dimensions and volume of the orbit and orbital fat in post-traumatic enopthalmos. Dentomaxillofacial radiology 2009;29:302-11.

52.Raymond J Fonseca, Oral and Maxillofacial – Trauma Volume:2; 3rd edition; W.B Saunders company: 2005

53.Risto K Kontio, Pekka Laine, Antero Salo, Pertti Paukku, Christian Lindqist, Ritta Surronen. Reconstruction of internal orbital wall fracture with iliac crest free bone graft: Clinical, Computed Tomography, and Magnetic Resonance Imaging follow-up study. Plastic Reconstructive Surgery 2006;118:1365.

54.Ronceivc R, Malinger B. Experience with various procedures in the treatment of orbital floor fractures. J. Maxillofac. Surgery 1981; 9: 81.

55.Sakakibara S, Hashikawa K, Terashi H, Tahara S. Reconstruction of the orbital floor with sheets of autogenous iliac cancellous bone. J Oral Maillofac. Surg. 2009;67:957-61.

56.Sandor GKB, Nish IA, Carmichael RP. Comparison of conventional surgery with motorized trephine in bone harvest from the anterior iliac crest. Oral Surgery Oral Medicine Oral Path Oral Radiology and Endodontics 2003;95:150-55.

57.Schantz JT, Hutmacher DW, Lam CX. Repair of calvarial defects with customised tissue-engineered bone grafts II. Evaluation of cellular efficiency and efficacy in vivo. Tissue Eng 2003;9:S127-S39.

58.Schantz JT, Lim TC, Ning C. Cranioplasty after trephination using a novel biodegradable burr hole cover: technical case report. Neurosurgery 2006; 58(1 Suppl):ONS-E176.

59.Schindler A, Je!coat R, Kimmel GL, Pitt CG, Wall ME, Zweidinger R. Biodegradable polymers for sustained drug delivery. Contemp Top Polym Sci 1977;2:251-89.

60.Serhan Tuncer, Reha Yavuzer, Sebahattin Kandal, YUcel H Demir, Selahattin Ozmen, Osman Latifoglu et al. Reconstruction of traumatic orbital floor fractures with resorbable mesh plate. Journal of Craniofacial Surgery 2007;18:598-605.

61.Seung Min Nam, Yong Bae Kim, Ho Seong Shin, Eun Soo Park. Orbital floor reconstruction considering orbital floor slope. Journal of Craniofacial Surgery 2011;22: 1479-82.

62.Sheldon M Mintz, Anna Ettinger, Timothy Schmakel. Contralateral coronoid process bone grafts for orbital floor reconstruction: An anatomical and clinical study. J Oral Maillofac. Surg. 1998;56:1140-44.

63.Shinichi Asamura, Yoshito Ikada, Kaazuhide Matsunga, Mitsuhiro Wada, Noritaka Isoga. Treatment of orbital floor fracture using a periosteum polymer complex. Journal of Cranio Maxillo-facial Surgery 2010;38.

64.A Siddique Robert H Mathog. A comparison of parietal and iliac bone grafts for orbital reconstruction : An anatomic and clinical study. J Oral Maillofac. Surg. 2000; 60:44-50

65.Siddique SA, Mathog RH. A comparison of parietal and iliac crest bone grafts for orbital reconstruction. J Oral Maillofac. Surg.2002;60:44-50.

66.Simon JB Prowse, Phobe M Hold, Robert f Gilour, Upasna Pratap, Eldon Mah, FrankW Kimble. Orbital floor reconstruction: A case for silicone a 12 years' experience. Journal of Plastic Reconstruc. and Aesthetic Surgery 2010;63.

67.Sindet – Pederson. Mandibular bone graft for reconstruction of alveolar cleft. J Oral Maillofac. Surg. 1988;46:533-7.

68.Smith B, Regan W Blow out fracture of orbit. Am J Opthalmol 1957;44: 733-9.

69.Strong E B. Endoscopic repair of orbital blow out fractures. Facial Plastic Surgery 2004;20:223-30.

70.Sun H, Mei L, Song C, Cui X, Wang P. The in-vivo degradation, absorption and excretion of PCL based implant. Biomterials2006;27:1735.

71.Takuya Higashino, Shinichi Hirabayashi, Tomoaki Eguchi, Yuki Kato. Straightforward factors for predicting the prognosis of blow-out fractures. Journal of Craniofacial Surgery 2011;22: 1210-14.

72.Tanag MA, Yano K, Hosokawa K. Orbital floor reconstruction using calcium phosphate cement paste; An animal study Plastic Reconstructive Surgery 2004;114:1826-31.

73.Veejayan Krishnan, James Johnson. Orbital floor reconstruction with autogenous mandibular symphyseal bone grafts. J Oral Maillofac. Surg.1997; 55:327-30.

74.Vert M, Li SM, Spenlehauer G, Guerin P. Bioresorbability and biocompatibility of aliphatic polyesters. J Mater Sci: Mater Med 1992;3:432- 46.

75.Wahid Abdullah, Bakiah Shaharuddin, Noor Hyati, MClinDent. Hospital Uniersity Sains Malaysia experience in orbital floor reconstruction; Autogenous graft vs Medpor. J Oral Maxillofac surg 2011;69:1740-44.

76.Waite PD, Clantons JT. Orbital floor reconstruction with lyophilized dura. J Oral Maxillofac Surgery 1988;46:727 .

77.Wang S, Xiao J, Liu L, Lin Y, Li X, Tang W, Wang H, Long J,Zheng X, Tian W. Orbital floor reconstruction: a retrospective study of 21 cases. Oral Surgery Oral Medicine Oral Path Oral Radiology and Endodontics 2008; 106:324-30.

78.Williams J.Li. Rowe & Williams Maxillofacial Injuries, Volume 1, 2nd Edition Churchill Livingstone, 1994.

79.Xianqun Fan, Huifang Zhou, Ming Lin, Yao Fu, Jin Li. Reconstruction of the complex orbital fractures with Computer Aided Design and Computer Aided Manufacturing technique. Journal of Craniofacial Surgery 2007;18.

80.Yavuzer R, Tuncder S, Basterzi Y, Isik I, Sari A, Latofoglu O. Reconstruction of orbital floor using solvent preserved bone graft. Plast Reconstr Surg 2004;113:33-34.

81.Yilmaz M, Vayvada H, Aydin E, Menderes A, Atabey. A Repair of fractures of the orbital floor with porous polyethylene implants. British Journal of Oral and Maxillofacial Surgery 2007;45:640-44.

82.Zaid H Baqain, Ziad Malkawi, Abeer Hadidi, Lamis D Rajab. Subtarsal approach for orbital floor repair: A long term follow-up of 12 cases in a Jordanian teaching hospital. J Oral Maillofac. Surg. 2008;66:45-50.

Annexure

CASE SHEET

History and clinical examination

1. Case No.
2. Date of Injury/ presentation to the department
3. Time elapsed
4. Name
5. Age/Sex
6. Occupation
7. Address
8. Telephone no
9. CHIEF COMPLAINT
10. HISTORY OF PRESENTING ILLNESS
    a. Date of Injury
    b. Date of presentation to our unit
    c. Time elapsed from the time of injury to initialization of the treatment
    d. Etiology of trauma
        i. Road Traffic accidents/ Usage of helmet
        ii. Alleged Assaults
        iii. Fall
        iv. Sports related injuries

v. Others

11. Past Medical History
12. 12.Past Dental History
13. Drug History and History of Allergy
14. Family History
15. Social History
16. Personal History
17. Previous Surgeries under Local anesthesia

General Examination

-Anemia

-Jaundice

-Cyanosis

-Clubbing

-Edema

-Lymphadenopathy

-CVS

-RS

-CNS

-GIT

LOCAL EXAMINATION

Extraoral Examination

Inspection

-Facial asymmetry / loss of malar prominence

-Edema

-Abrasion

-Laceration

-Soft tissue Loss

-Ocular injuries

-Ocular displacement

Exophthalmos

Enophthalmos

Unequal Pupillary level

-Displacement of the palpebral fissure (Mongoloid/Anti-Mongoloid slant)

-Limitations in Eye movements

-Diplopia

-Circumorbital ecchymosis

-Circumorbital edema

-Subconjunctival haemorrhage

-Mouth Opening

-Jaw movement

-Signs of infection

Palpation

-Tenderness/Pain

-Crepitus

-Mobility

-Step deformity

-Paresthesia

INTRAORAL EXAMINATION

Inspection

-Trismus

-Teeth Present

a. Missing

b. Avulsed

c. Subluxated

-Oral Hygiene-Good/Fair/Poor

-Occlusion- Normal/Deranged

-Open Bite

- Step Deformity

- Soft tissue laceration

-Hematoma/ ecchymosis in the upper canine region

- Exposed bone

-Signs of infection

Palpation

-Mobility of teeth

-Insensibility of the anterior teeth

-Mobility of # Segment

-Deformity of the zygomatic buttress

-Tenderness

-Step deformity

CLINICAL IMPRESSION

INVESTIGATIONS

Radiographs

-Para nasal sinus view

-Submentovertex projection

CT scan

Axial/ coronal sections with 3D reconstruction

RADIOGRAPHIC IMPRESSION

FINAL DIAGNOSIS

TREATMENT PLAN

INFORMED CONSENT

EFFICACY OF RESORBABLE (POLY CAPRONOLACTONE) MESH IN THE TREATMENT OF ORBITAL BLOW OUT FRACTURES

Patient's Identification No: _____ Patient's Name: _____
Patient's DOB: _____ _____ _____
dd mm yyyy

I confirm that I have read and understood the Information Sheet for the above study. I have had the opportunity to ask questions and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

I understand that the Clinical study personnel, the Ethics Committee and the Regulatory Authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to the third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

I agree not to withhold any information about my health from the investigator and will convey the same truthfully.

I agree to take part in the above study and to comply with the instructions given during the study and to faithfully co-operate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby consent to participate in this study & I understand that I'll be treated by surgical procedure under general anaesthesia for correction of fracture in my orbit with resorbable mesh and I was well informed about the complications associated with it & I agree for the same.

I consent to give my medical history, undergo complete physical examination and diagnostic tests including hematological, biochemical and urine examination etc.

Signature / Thumb Impression: _____ Place_____Date_____

Patient's Name & Address: _____

Signature of the Investigator: _____Place_____ Date_____

Study Investigator's Name: _____

Institution: _____

* Signature of the Witness: _____Place_____ Date_____
* Name & Address of the Witness _____
_____ *Mandatory for uneducated patients (Where thumb impression has been provided above)

<u>சுய ஒப்புதல் படிவம்</u>

ஆய்வு செய்யப்படும் தலைப்பு

"ஈர்த்துக்கரையும் வலைக்கண்ணி கொண்டு விழிக்குழி சக்கரக்குழற்பட்டை எலும்புமுறிவு சிகிச்சை செய்தல்"

ஆராய்ச்சி நிலையம் : அரசு பல் மருத்துவக் கல்லூரி,
சென்னை - 600 003.

பங்கு பெறுபவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்கு பெறுபவரின் பிறந்த தேதி: ...../ ...../ .....
தேதி மாதம் வருடம்

அறுவை சிகிச்சை சம்பந்தமாக நான் மேலே கூறப்பட்ட தகவல் படிவத்தை முழுமையாக படித்துப் பார்த்தேன் என்று உறுதி கூறுகிறேன்.

நான் இது தொடர்பான அனைத்து கேள்விகளுக்கும் நிறைவான பதில்கள் பெறப்பட்டேன்.

இந்த ஆய்வின் எனது பங்கு தன்னிச்சையானது என்றும் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து சட்ட உரிமைகள் பாதிக்கப்படாமல் விலகிக் கொள்ள சம்மதிக்கிறேன்.

மருத்துவ ஆய்வு அதிகாரிகள், எனது சிகிச்சை தொடர்பான பதிவேடுகளை பார்வையிடவும் எந்த நேரத்திலும், ஆய்வில் இருந்து நான் விலகினாலும் பார்வையிட சம்மதிக்கிறேன். எனது அடையாள குறிப்புகள் மூன்றாவது நபருக்கு தெரிவிக்கப்பட மாட்டாது என்று புரிந்து கொண்டேன்.

இந்த ஆய்வு அறிக்கைகளை பயன்படுத்தவும், வெளியிடவும், நான் சம்மதிக்கிறேன். ஆய்வாளர் எனது மருத்துவக் குறிப்புகளை வெளியிட தடையாக இருக்க மாட்டேன் என உண்மையாக சம்மதிக்கிறேன்.

நான் இந்த ஆய்வுக்கு முன்னர் கூறிய மருத்துவ குறிப்புகளின்படியும் உண்மையாக சம்மதிக்கிறேன். மேலும் எனக்கு உடல்நிலை சரியில்லாத பட்சத்தில் ஆய்வாளர்களுக்கு தெரியப்படுத்த சம்மதிக்கிறேன்.

பொது மயக்க மருத்துவ முறையில் ஈர்த்துக்கரையும் வலைக்கண்ணி கொண்டு எனது கண் எலும்பு முறிவை சரி செய்து கொள்ள ஒப்புதல் அளிக்கிறேன். இந்த அறுவை சிகிச்சை முறையில் ஏற்படும் அனைத்து பக்க விளைவுகளை மருத்துவர் மூலம் அறிந்து கொண்டேன்.

நான் எனது மருத்துவ குறிப்புகளை தரவும், மேலும் முழு உடல் பரிசோதனைக்கும் இரத்தம், சிறுநீர், மற்றும் உயிர் வேதியியயல் நோய் அறிதல் சோதனைகளுக்கும் முழு ஒப்புதல் அளிக்கிறேன.

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி

ஆய்வாளரின் பெயர் .....

INFORMATION SHEET

- We are conducting a study on **"Efficacy of resorbable mesh (polycaprolactone) in the treatment of orbital blow out fractures".**
- The purpose of this study is to assess the usefulness of polycaprolactone resorbable mesh in the reconstruction of orbital floor in blow out fractures.
- The privacy of the subjects in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of parent/ guardian

Date:

<u>சுய ஒப்புதல் படிவம்</u>

ஆய்வு செய்யப்படும் தலைப்பு

"ஈர்த்துக்கரையும் வலைக்கண்ணி கொண்டு விழிக்குழி சக்கரக்குழற்பட்டை எலும்புமுறிவு சிகிச்சை செய்தல்"

ஆராய்ச்சி நிலையம் : அரசு பல் மருத்துவக் கல்லூரி,
சென்னை - 600 003.

பங்கு பெறுபவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்கு பெறுபவரின் பிறந்த தேதி: ...../ ...../ .....
தேதி மாதம் வருடம்

அறுவை சிகிச்சை சம்பந்தமாக நான் மேலே கூறப்பட்ட தகவல் படிவத்தை முழுமையாக படித்துப் பார்த்தேன் என்று உறுதி கூறுகிறேன்.

நான் இது தொடர்பான அனைத்து கேள்விகளுக்கும் நிறைவான பதில்கள் பெறப்பட்டேன்.

இந்த ஆய்வின் எனது பங்கு தன்னிச்சையானது என்றும் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து சட்ட உரிமைகள் பாதிக்கப்படாமல் விலகிக் கொள்ள சம்மதிக்கிறேன்.

மருத்துவ ஆய்வு அதிகாரிகள், எனது சிகிச்சை தொடர்பான பதிவேடுகளை பார்வையிடவும் எந்த நேரத்திலும், ஆய்வில் இருந்து நான் விலகினாலும் பார்வையிட சம்மதிக்கிறேன். எனது அடையாள குறிப்புகள் மூன்றாவது நபருக்கு தெரிவிக்கப்பட மாட்டாது என்று புரிந்து கொண்டேன்.

இந்த ஆய்வு அறிக்கைகளை பயன்படுத்தவும், வெளியிடவும், நான் சம்மதிக்கிறேன். ஆய்வாளர் எனது மருத்துவக் குறிப்புகளை வெளியிட தடையாக இருக்க மாட்டேன் என உண்மையாக சம்மதிக்கிறேன்.

நான் இந்த ஆய்வுக்கு முன்னர் கூறிய மருத்துவ குறிப்புகளின்படியும் உண்மையாக சம்மதிக்கிறேன். மேலும் எனக்கு உடல்நிலை சரியில்லாத பட்சத்தில் ஆய்வாளர்களுக்கு தெரியப்படுத்த சம்மதிக்கிறேன்.

பொது மயக்க மருத்துவ முறையில் ஈர்த்துக்கரையும் வலைக்கண்ணி கொண்டு எனது கண் எலும்பு முறிவை சரி செய்து கொள்ள ஒப்புதல் அளிக்கிறேன். இந்த அறுவை சிகிச்சை முறையில் ஏற்படும் அனைத்து பக்க விளைவுகளை மருத்துவர் மூலம் அறிந்து கொண்டேன்.

நான் எனது மருத்துவ குறிப்புகளை தரவும், மேலும் முழு உடல் பரிசோதனைக்கும் இரத்தம், சிறுநீர், மற்றும் உயிர் வேதியியயல் நோய் அறிதல் சோதனைகளுக்கும் முழு ஒப்புதல் அளிக்கிறேன.

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி

ஆய்வாளரின் பெயர் .....